

February 15, 2008

David Cramer
Mirant Mid-Atlantic, LLC
8301 Professional Place; Suite 230
Landover MD 20785

RE: Review of the Earth Tech, Inc. *Summary Report and Technical Report – Evaluation of Health Effects from Increased PM_{2.5} To Residents Near the Potomac River Generating Station (PRGS)* dated January 2008 and Comments on the *Special Environmental Analysis For Actions Taken under U.S. Department of Energy Emergency Orders Regarding Operation of the Potomac River Generating Station in Alexandria, Virginia* Prepared by the US DOE

Dear Mr. Cramer:

We have reviewed the Summary Report and Technical Report concerning the proposed Stationary Source Permit to Operate (two-stack version) for the Mirant Potomac River Generating Station (PRGS) that were issued by Earth Tech, Inc. in January 2008. The Earth Tech reports provide an incomplete description of the work conducted, making a rigorous critique of its work difficult, but the information that is available is sufficient to: (1) show that the Earth Tech approach is deficient and inappropriate to an analysis of the proposed permit and (2) identify errors in the Earth Tech methodology that render the Earth Tech conclusions unreliable. This letter describes the findings of our review of the Earth Tech reports and also includes a discussion of the Special Environmental Analysis (SEA) previously conducted by the USDOE for the PRGS.¹

Earth Tech Ignores the Fact that PM_{2.5} Levels in the Area are Adequately Protective of Public Health

The Earth Tech report attempts to calculate the incremental change in adverse human health effects and mortality in the surrounding population that are purportedly related to emissions from the PRGS. In order to conduct this evaluation, Earth Tech pairs the predictions of air emissions modeling with an EPA application known as the Environmental Benefits Mapping and Analysis Program (BenMAP). BenMAP was designed by the EPA to estimate the

¹ Though the SEA is not applicable to a review of the proposed two-stack permit, Earth Tech references the document in its report. We have therefore included selected comments on the SEA in this letter.

health benefits associated with improvements in air quality and has typically been used by the agency to assess the benefits of proposed regulatory action (such as the Clean Air Interstate Rule, CAIR).

Earth Tech's application of BenMAP to the PRGS is novel and ignores the wider regulatory framework that has been put in place to protect public health and air quality in Alexandria. In particular, the approach appears to have been conducted without consideration for the published National Ambient Air Quality Standards (NAAQS) for PM_{2.5} or the State Implementation Plan (SIP) process, which is ultimately designed to ensure attainment of the NAAQS, and is a cornerstone of the Clean Air Act.

Fine particulate matter (PM_{2.5}), the pollutant that is the primary focus of the Earth Tech report, is a regulated Criteria Air Pollutant, and EPA has recently revised the NAAQS for PM_{2.5}. NAAQS are established by EPA, based on a review of the best available science, to be protective of human health, including sensitive populations. Though Alexandria is part of the larger Washington metropolitan area PM_{2.5} nonattainment area, recent sampling at the EPA PM_{2.5} monitor closest to the PRGS (at S 18th and Hayes Street in Arlington) shows that PM_{2.5} concentrations in the area are below the health protective NAAQS concentrations (for both the annual and 24-hour averaging periods) (USEPA 2008). Recent PM_{2.5} monitoring by the PRGS during plant operation at the locations predicted to be maximally effected by the plant also shows compliance with the NAAQS (ENSR 2007). Finally, the "Alexandria Summary" data cited by Earth Tech as being provided by VDEQ similarly confirms the area is in compliance with the NAAQS, and, therefore, local PM_{2.5} concentrations are presumptively protective of human health.

While EPA acknowledges there are health risks with PM_{2.5} both above and below the NAAQS, and BenMAP can be used to estimate increased morbidity and mortality and associated costs with any increment in PM_{2.5} concentrations, EPA has defined the NAAQS as the appropriate threshold for protection of public health. Accordingly, with actual PM_{2.5} measurements (which, importantly *include* the contribution of the PRGS) showing levels below the NAAQS, there is no evidence of unacceptable health risks in Alexandria due to PM_{2.5}. Therefore, there does not appear to be a regulatory basis for the consideration of Earth Tech's adverse health effects evaluation during the review of the two-stack permit, particularly since impacts are reduced under the proposed permit.²

² While regulation of PM_{2.5} emissions in the Alexandria area may be required to ensure attainment of the PM_{2.5} NAAQS in other parts of the region that are not currently in attainment, such regulation will be appropriate only once the Virginia State Implementation Plan has been prepared.

Additionally, a comparison of PM_{2.5} monitoring data from Marina Towers with monitoring data from Federal Reference Monitors in the Virginia/Maryland/DC region (as shown in Figure 1) shows that PM_{2.5} concentrations consistently trend together throughout the region. In other words, on days when higher PM_{2.5} concentrations were measured at Marina Towers, higher concentrations were generally seen across the region, at both urban and rural monitors, some many miles from the PRGS. This suggests that regional PM_{2.5} levels are driven by upwind emissions sources, rather than emissions sources within the region, and that higher PM_{2.5} concentrations at Marina Towers on certain days are almost certainly due to the regional influence, rather than emissions from the PRGS, which does not appear to have a significant effect on local PM_{2.5} concentrations.

The Proposed Two-Stack Configuration Provides a Measurable Health Benefit Contrary to Earth Tech's Assertion

The Earth Tech approach calculates health risks purportedly associated with emissions under the two-stack permit but does not include a proper baseline or comparison point for the calculated risks. The Earth Tech approach calculates the health risks purportedly associated with the incremental PM_{2.5} concentrations that their modeling predicts for the two-stack permit. In their approach, these incremental PM_{2.5} concentrations are added to the currently monitored PM_{2.5} background in Alexandria. There is a significant flaw with this approach that completely invalidates their findings of an increased health risk.

The PRGS is a currently operating facility, whose emissions are already included in the ambient PM_{2.5} concentrations measured in the area. The Earth Tech approach neglects this and instead treats emissions under the two-stack permit as if the facility was not currently in operation. This places the proposed permit in the incorrect context and suggests that PM_{2.5} emissions from the facility and ambient PM_{2.5} levels in Alexandria would actually worsen under the proposed permit, leading to an increase in predicted adverse health effects.

A proper application of BenMAP would show health benefits from the proposed two-stack permit. BenMAP has a baseline condition and a control condition. In a proper application of BenMAP, the baseline grid would reflect current operating conditions at PRGS, and the control grid would correspond to operation under the proposed two-stack permit. The control condition would be determined from measurements of PM_{2.5} in the area, subtracting the influence of existing PRGS emissions, and adding the projected impacts under the two-stack configuration. Due to the lower emissions and better dispersion conditions under the two-stack configuration, the facility's contribution to ambient PM_{2.5} concentrations would be lower under the proposed permit. The delta (difference between baseline and control) in ambient

concentration from a correct analysis would show a health benefit rather than the adverse health effects (and increased costs) Earth Tech erroneously estimates.

Earth Tech Has Failed to Conduct a Complete Cost Benefit Analysis for PRGS

The Earth Tech approach incorporates only air emissions modeling using AERMOD and a projection of the health risks arising from the modeled incremental change in PM_{2.5} using BenMAP. EPA generally uses BenMAP during the analysis of a proposed regulation in a somewhat similar manner (though the analysis is regional or national in scope, rather than focusing on a single facility) – to assess the health and monetary benefits associated with an improvement in modeled air quality under the proposed regulation. However, this is only one part of the cost/benefit analysis conducted by EPA. For example, the Regulatory Impact Analysis for the Final Clean Air Interstate Rule (USEPA 2005) included not only the use of BenMAP but the use of the Integrated Planning Model (IPM) and other systems to assess the costs and risks associated with the proposed action (in the case of CAIR, these included costs to the regulated facilities; increased coal consumption and mining, with the increased risk of accidents; and the potential for increased retail electricity costs, with the associated risks to the poor), to confirm that modeled benefits justify the cost.

All human activities involve some risk, and all industrial activities have a measurable adverse effect on the environment. Because many industrial activities, including electrical power generation, are also associated with measurable human benefit, it is important to balance projected risks with the benefits of industrial activities. While there is a risk associated with operation of any power plant, including the PRGS, the Earth Tech approach is incomplete because it does not properly balance that risk with the risks of alternative permitting or power production schemes, or the benefits of the proposed permit with the benefits of alternative schemes.

The facility provides a needed power contribution to the electrical grid, and, in its absence, additional power generation would be required at another location (through increased power production at an existing facility). Calculated health risks of some magnitude would then be shifted to the site of the increased generation, not removed altogether. In the absence of more complete context, the Earth Tech approach suggests that a risk deferral through rejection of the proposed permit that would not actually be attainable.

Errors in Earth Tech's Approach Invalidates their Conclusions

Though it is difficult to fully critique the Earth Tech reports based on the limited information provided (no modeling files were provided), it is clear that the approach suffers from several technical flaws, in addition to the more conceptual issues described above. We have

divided our discussion of these errors into three categories, air modeling, assessment of health effects, and assessment of affected population.

Air Modeling Errors

Earth Tech predicts $PM_{2.5}$ concentrations using “*AERMOD for receptors within an 800 meter grid around PRGS and for the most highly impacted receptors at the Marina Towers condominium complex.*” Underlying assumptions in their model are listed in Table 1 of their report, and there are several problems with these assumptions. First, Earth Tech assumes a primary $PM_{2.5}$ emission rate of 0.030 lbs/MMBTU, but recent stack testing suggests that actual emission rates are on the order of 0.014 lbs/MMBTU instead or approximately half that used by Earth Tech (TRC 2006). Earth Tech then increases these primary emissions to 0.055 lbs/MMBTU to account for secondary $PM_{2.5}$ formation as a result of atmospheric reaction of sulfur dioxide emitted by the PRGS. This is inappropriate because these secondary reactions take place relatively slowly in the atmosphere, and secondary $PM_{2.5}$ would not be expected to form until the emitted sulfur dioxide has moved several miles downwind from the facility. For example, the Earth Tech report relies on a 7% conversion rate of sulfur dioxide to $PM_{2.5}$ (apparently from Azad and Kitada (1998), cited in the DOE SEA), but apparently misunderstands the authors’ findings. In this article, the authors report that only 0.3% of emitted sulfur dioxide is converted to $PM_{2.5}$ within the first hour after emission, which translates to 7% within 24 hours, not that 7% of sulfur dioxide is instantaneously converted to $PM_{2.5}$ as Earth Tech assumes. Clearly, sulfur dioxide emitted by the facility will be beyond the 800-meter modeling grid used by Earth Tech within an hour, so the addition of secondary $PM_{2.5}$ to stack emissions is inappropriate and incorrect. Thus, Earth Tech overstates impacts by more than 3-fold from use of estimated rather than measured $PM_{2.5}$ emission rates.

The Earth Tech model also assumes that the facility will be operated in the worst-case scenario 1D, five boilers at mid-load, continuously. For operational reasons, scenario 1D would be expected to occur for only a small portion of time, since it is generally more efficient to operate fewer boilers at higher loads rather than several boilers at mid loads. Therefore, scenario 1D would generally occur only when production levels at the facility are increasing or decreasing. Since emissions under scenario 1D would not be expected to occur consistently throughout the year, the Earth Tech model does not accurately reflect actual annual site emissions under the proposed two-stack permit and is overly conservative.

Earth Tech has also failed to evaluate the accuracy of its model for the area immediately surrounding the PRGS. Comparison of AERMOD predictions to actual monitoring shows that AERMOD significantly overestimates air pollution levels resulting from plant operations. Given this known discrepancy, Earth Tech was deficient in not considering the model's predictive limitations.

Errors in Assessments of Health Effects

When calculating the health effects and increase in mortality associated with modeled PM_{2.5} increments, Earth Tech relies upon the use of maximum daily PM_{2.5} concentrations to generate its upper bound risk estimates. This is incorrect and substantially overstates risks. In reviewing the Pope et al. (2002) epidemiology study, which Earth Tech relies on to provide the relationship between ambient PM concentration and premature mortality, *the annual average PM_{2.5} concentration* is the metric evaluated by Pope et al. (2002), and is, therefore, the appropriate parameter to use. Inclusion of health risks associated with the maximum daily PM_{2.5} concentration is incorrect and misleading. Since more than 90 percent of the detriment Earth Tech attributes to the PRGS operation is associated with their estimate of premature mortality, this error has a significant affect on the cost estimates. Earth Tech also applies the wrong exposure metric (maximum daily v. annual average concentration) to the chronic bronchitis endpoint, which constitutes the next highest contributor to Earth Tech's total cost estimate. Disregarding all other errors, rectifying this error alone results in a decrease in the annual predicted cases of premature mortality from 4.47 to less than one.

Errors in Population Distribution

In order to calculate health risks and costs associated with the modeled PM_{2.5} increment, Earth Tech must estimate populations within the 800-model grid, and within each of the grid cells. BenMAP is used to estimate health effects based on Earth Tech's estimate of PM_{2.5} concentrations in each grid cell and the number of individuals (population) in each cell. According to the Earth Tech report, they relied on Abt Associates to conduct this population evaluation, and few details of the approach are provided. The evaluation concluded that approximately 4,700 people live within the modeling domain, and that 495 residents live within Marina Towers.

The Earth Tech report indicates that the population within the modeling domain was distributed across each model grid cell using population data from the 2000 US Census blocks. Though the description of the procedure is scant, there are significant potential errors in this distribution of population, particularly since it was apparently

based only on Census block boundaries, and not the actual distribution of residents in the modeling grid. The attached Figure 2a displays Figure 5 of Earth Tech's Technical report, which shows the annual $PM_{2.5}$ increments attributed to the proposed two-stack operation as estimated by Earth Tech. As this figure shows, Earth Tech estimates that the $PM_{2.5}$ increment ranges from 0.24 ug/m^3 (yellow) to 3.35 ug/m^3 (blue).³ In Figure 2b, the Earth Tech grid is superimposed on an aerial photograph of the local area around PRGS.

Figure 3 shows the 2000 Census blocks in the area. Each of the irregularly shaped polygons in Figure 3 is a Census block. By reviewing Figure 3, it is obvious that certain Census blocks around the PRGS include not only populated areas, but also areas where there are no residents. For example, the block containing Marina Towers stretches north through National Park Service land. Additionally, a review of Figures 4 and 5, showing local zoning, demonstrates that residential land use within the Earth Tech modeling grid is actually relatively limited. The Census block boundaries suggest that people live within areas of the modeling grid where there are no residents. Since the Earth Tech approach apparently depended only on Census block boundaries, it would have inappropriately distributed population to modeling grid cells where there are no residential receptors. For example, in the pink grid cells shown directly north of the facility in Figure 2a and 2b.

This error is particularly significant when the annual $PM_{2.5}$ concentrations predicted by the Earth Tech model are compared to areas that are actually residential, as shown in Figure 6. There is little evidence of the blue and pink grid cells in the figure.⁴ This figure demonstrates that the areas predicted to be most affected by the Earth Tech model (to experience the largest incremental increase in $PM_{2.5}$) are actually non-residential. In fact, a review of Figure 7 shows that there are no *buildings* in many of the most affected areas. Since the Earth Tech population distribution, as described, would have allocated population to these non-residential areas with a higher predicted $PM_{2.5}$ concentrations, the approach would have calculated undue health risks in these areas, resulting in a potentially significant elevation of predicted risk and cost across the modeling grid.

³ As will be evident from the following discussion, Earth Tech's estimates of $PM_{2.5}$ increments in the residential area are closer to the lower end of the spectrum.

⁴ The limited evidence of higher concentrations adjacent to the coal pile is likely an artifact created from assumptions relating to ground level fugitive emissions of PM_{10} , which Earth Tech does not describe in its reports.

Additionally, it appears from the Earth Tech report, that the entire population of Marina Towers (more than 10% of the total grid population) may have been considered twice during the summation of risks and associated costs across the modeling grid:

Residents of the Marina Towers were evaluated as part of the larger 800 meter grid and independently because of the increased concentrations of PM_{2.5} that were evident within the modeled data for the upper floors of this complex.

This quote also indicates that the entire population of Marina Towers was assumed to be located on the upper floors (or perhaps roof) of the complex. Since the model predictions at ground-level and roof-level are significantly different, particularly for the 24-hour averaging period relied upon by Earth Tech to produce its upper bound risks and costs, this population placement would inappropriately inflate the risk estimates.

DOE SEA is not Applicable to the Proposed Permit

The DOE conducted the SEA to assess the environmental effects of the previous DOE Order. The DOE Order lapsed in the summer of 2007 and no longer affects operations at the PRGS. The SEA is not applicable to the proposed two-stack permit. Regardless, Earth Tech discusses the SEA in Section 5 of their Technical Report and attempts to compare the health effects predicted by the SEA to their own predictions. This comparison is incomplete, however, because it implies that the DOE SEA found an increase in health risks to be associated with operation of the PRGS under the DOE Order. In fact, the SEA predicted that health risks under the Order would be lower than risks that existed before the plant shutdown in 2005. Since the two-stack permit would include enhanced dispersion of pollutants within the immediate vicinity of the plant, and PM_{2.5} emission rates are lower than those assumed by the SEA (based on stack test data) (TRC 2006), extrapolation of the SEA findings would suggest that predicted health effects under the proposed permit would be still lower than those under the Order.

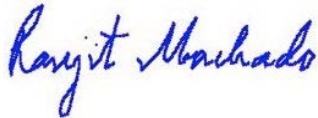
Since the SEA is not directly applicable to the proposed two-stack permit, we have not conducted an in-depth review of the methodology used by the DOE. However, the SEA appears to model PM_{2.5} emission rates that are higher than actual emission rates (as determined by stack test), and may make inappropriate use of Azad and Kitada (1998), though it is unclear whether secondary particulate formation was considered in their near-field analysis or only their eastern seaboard analysis. The DOE also used default model assumptions for building downwash when modeling emissions from the PRGS, rather than using equivalent building dimensions (EBDs). Given the known discrepancy between modeling and monitoring results near the facility, the selection of default downwash assumptions added inappropriate conservatism to the DOE model.

Additionally, DOE inappropriately ignored the facility's current contribution to $PM_{2.5}$ levels in the area, resulting in an inaccurate control case for their assessment of health effects. The SEA also provides little detail on the extrapolation of health risks from modeled results.

Conclusion

In conclusion, our review of Earth Tech's report indicates that their approach is inappropriate, incomplete, and incorrect. Measurements of $PM_{2.5}$ concentrations in the area confirm that levels are adequately protective of public health. Please feel free to contact me if you have any questions or comments regarding this letter.

Sincerely,



Ranjit J. Machado, P.E.
Principal

Citations

Azad and Kitada. 1998. Characteristics of the air pollution in the city of Dhaka, Bangladesh in winter. *Atmospheric Environment*. 32(11):1991-2005.

Department of Energy (DOE). 2006. Special Environmental Analysis for Actions Taken under U.S. Department of Energy Emergency Orders Regarding Operation of the Potomac River Generating Station in Alexandria, Virginia. DOE/SEA-04.

Earth Tech. 2008. Technical Report. Evaluation of Health Effects from Increased PM_{2.5} to Residents near the Potomac River Generating Station. January.

ENSR. 2007. Analysis of PM_{2.5} Concentrations Measured on Top of Marina Towers and at the Southeast Fenceline – November 20, 2007. November.

Pope et al. 2002. Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. *Jama*. 287(9):1132-41.

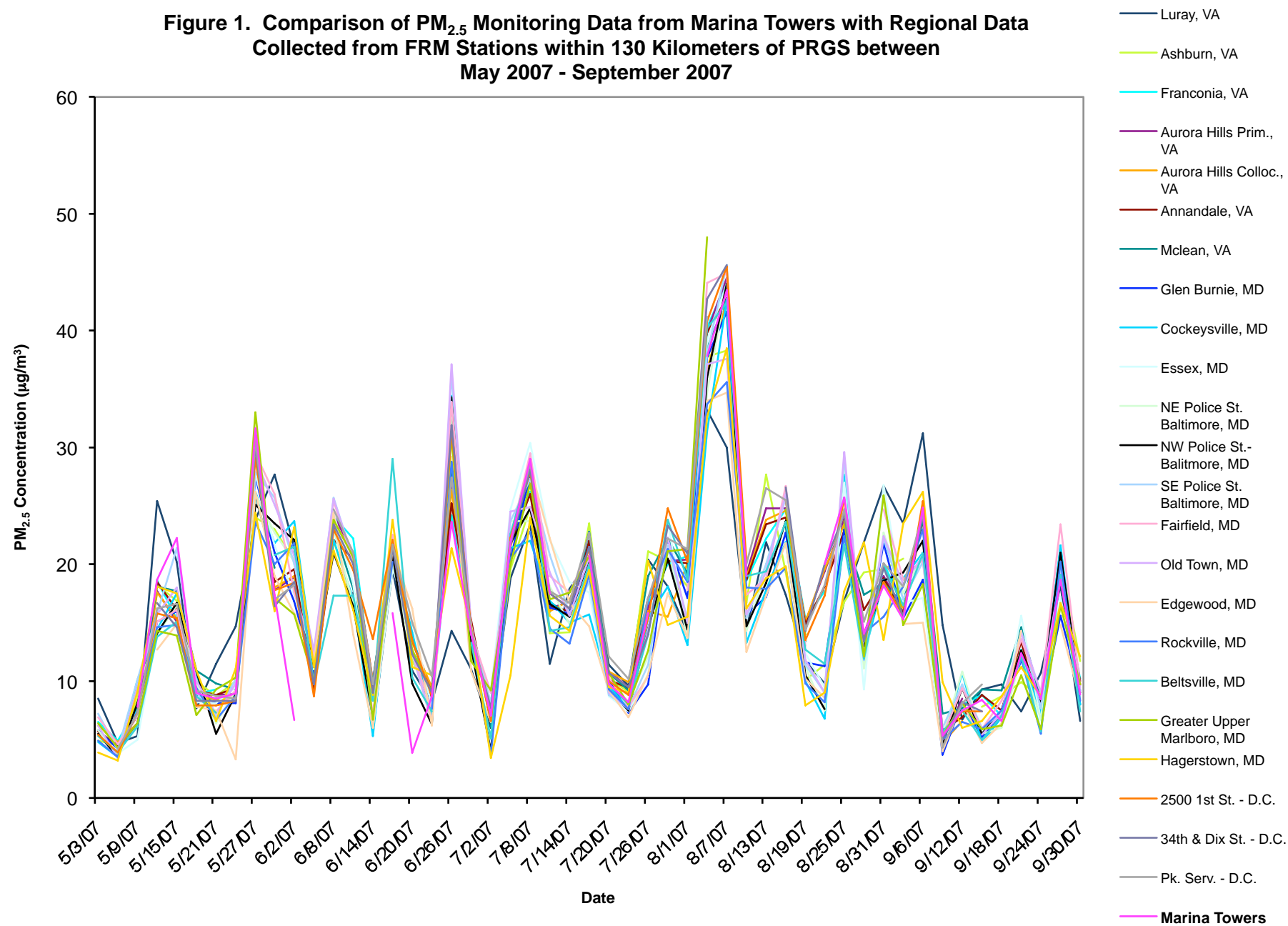
TRC. 2006. Final Report – Particulate Emissions (PM₁₀, PM_{2.5} and Condensable) and Hydrochloric Acid Emissions Testing at Potomac River Generating Plant Alexandria, Virginia). December.

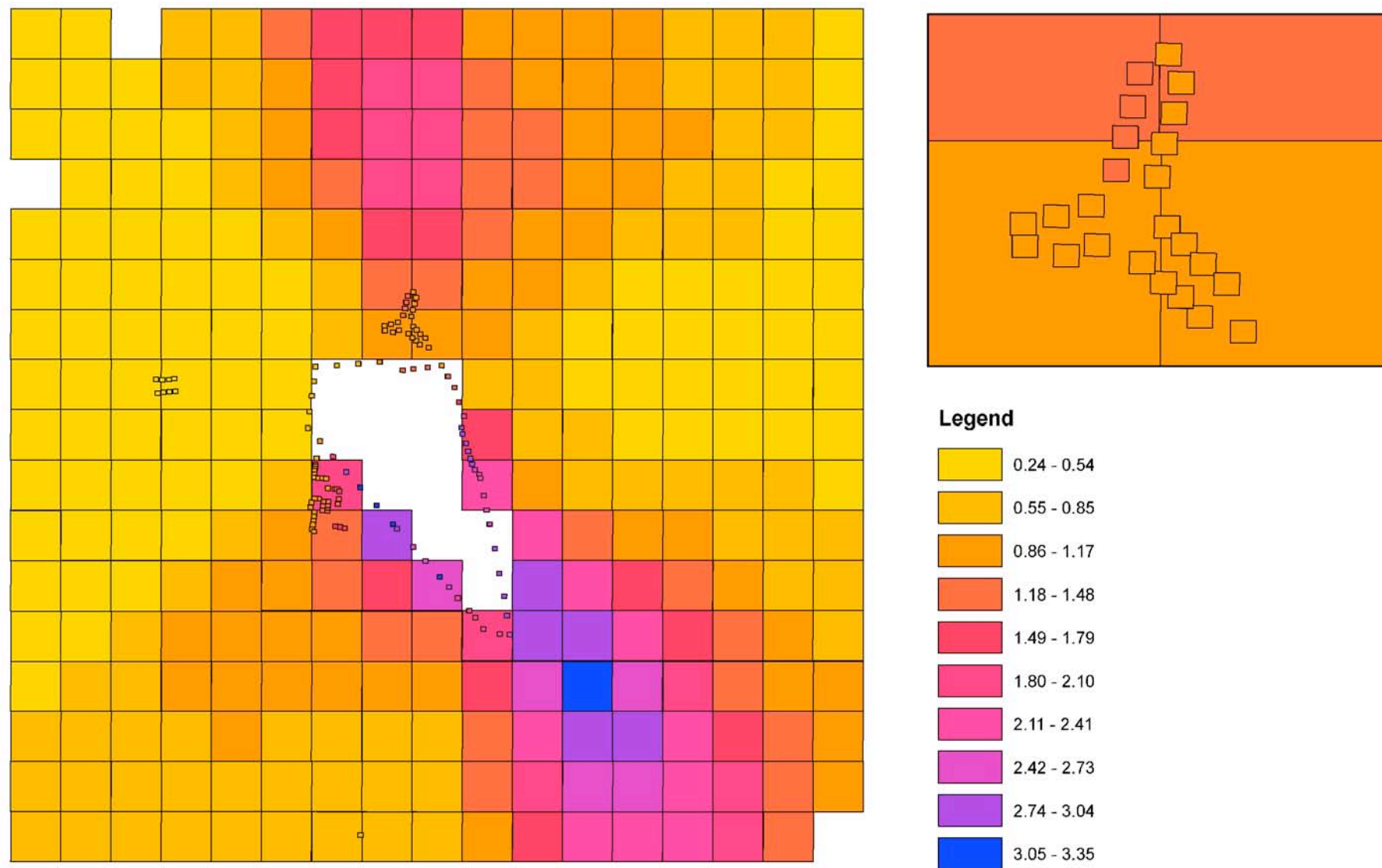
United States Environmental Protection Agency (USEPA). 2005. Regulatory Impacts Analysis for the Final Clean Air Interstate Rule. EPA-425/R-05-002. March.

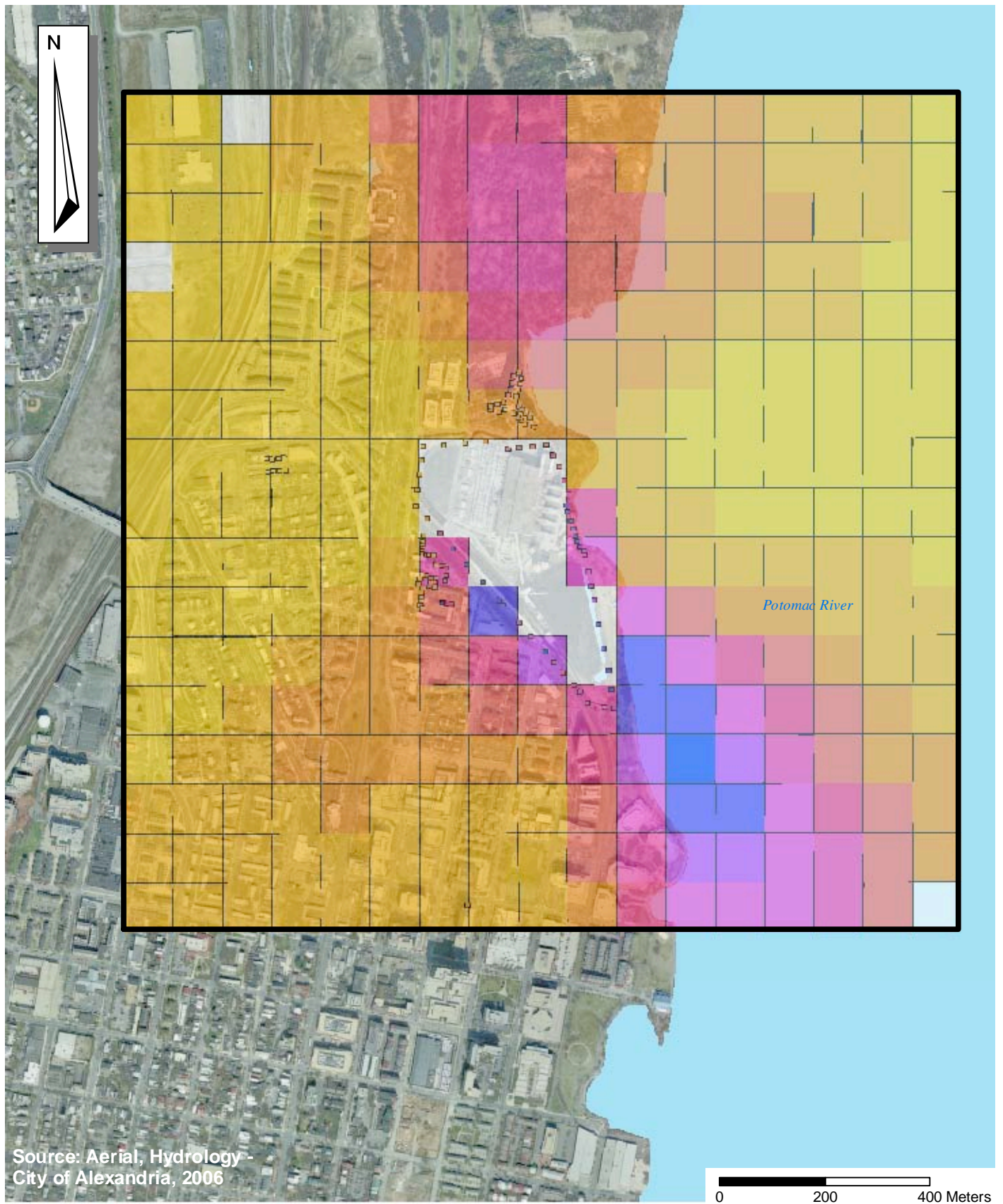
USEPA. 2008. Query AQS Data. Available at: <http://www.epa.gov/aqspubl1/>. Downloaded on February 4.

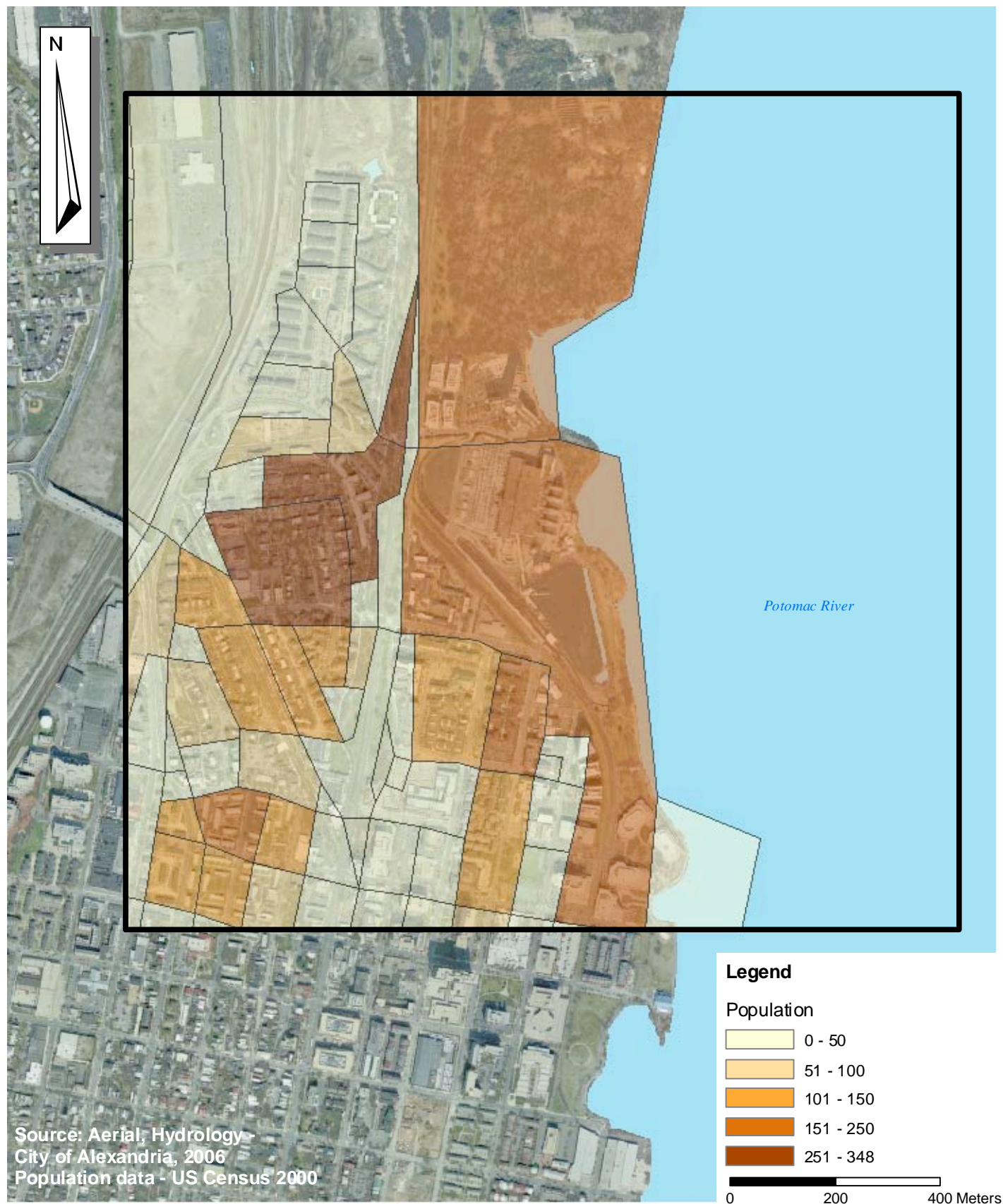
FIGURES

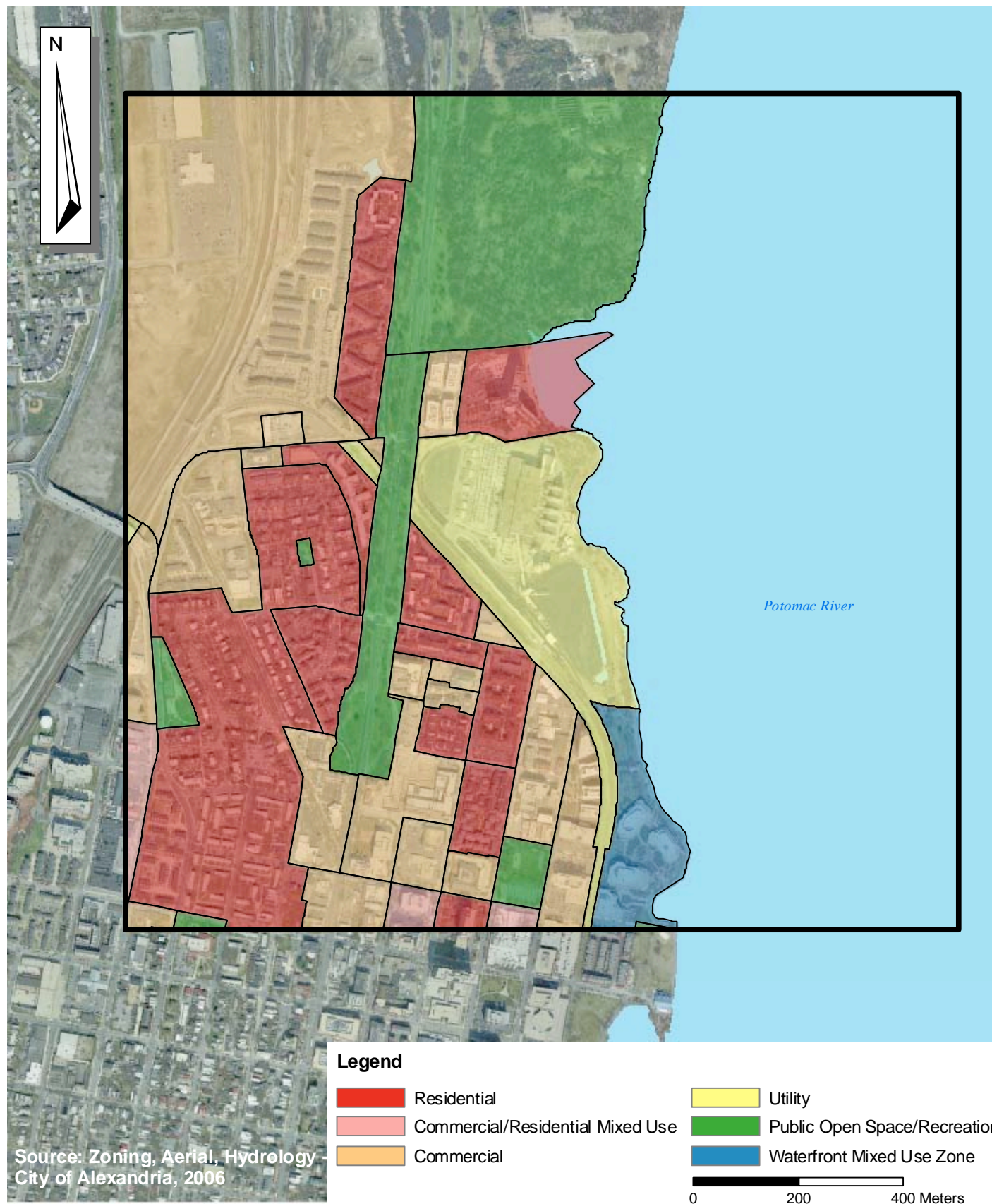
Figure 1. Comparison of PM_{2.5} Monitoring Data from Marina Towers with Regional Data Collected from FRM Stations within 130 Kilometers of PRGS between May 2007 - September 2007

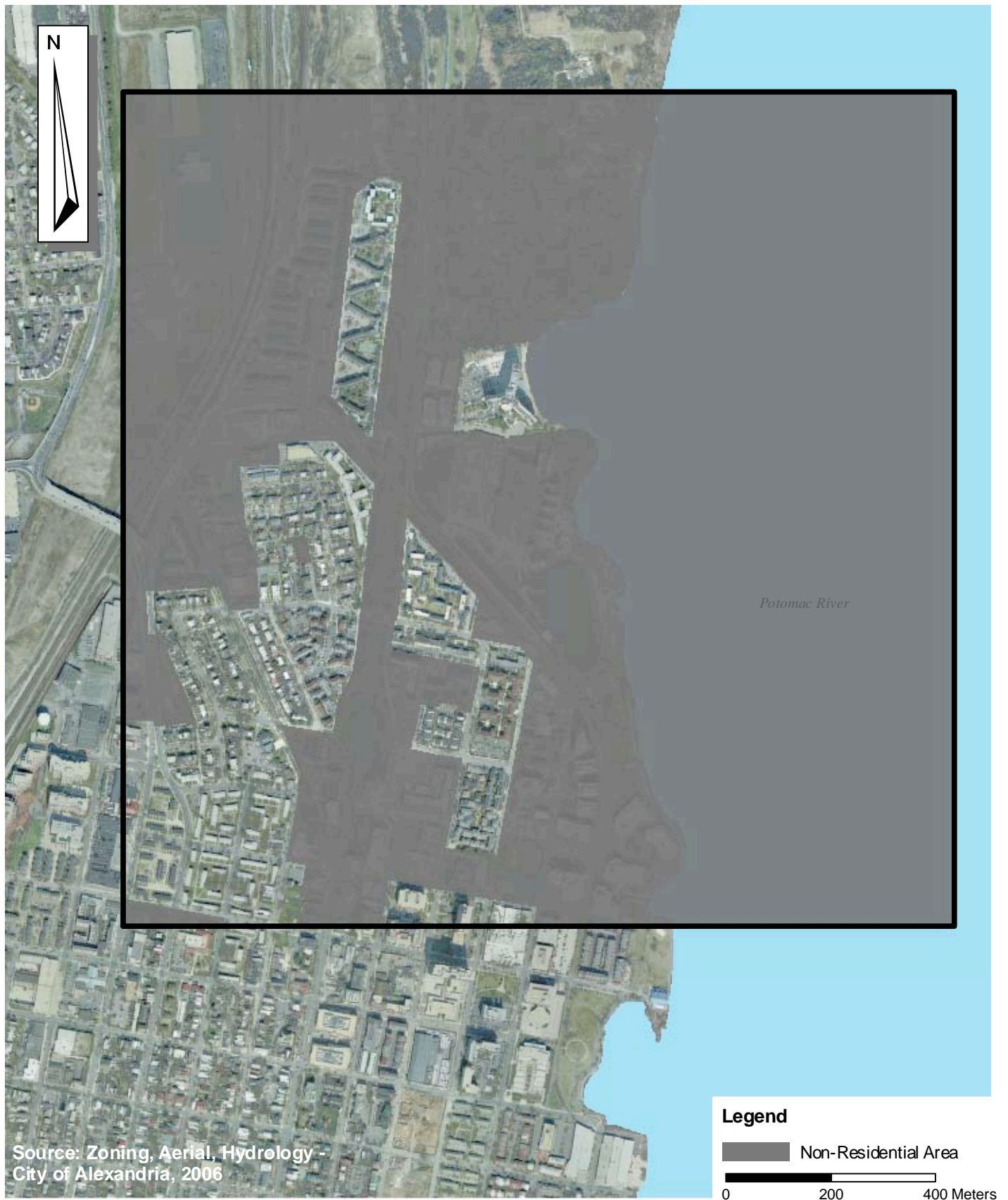


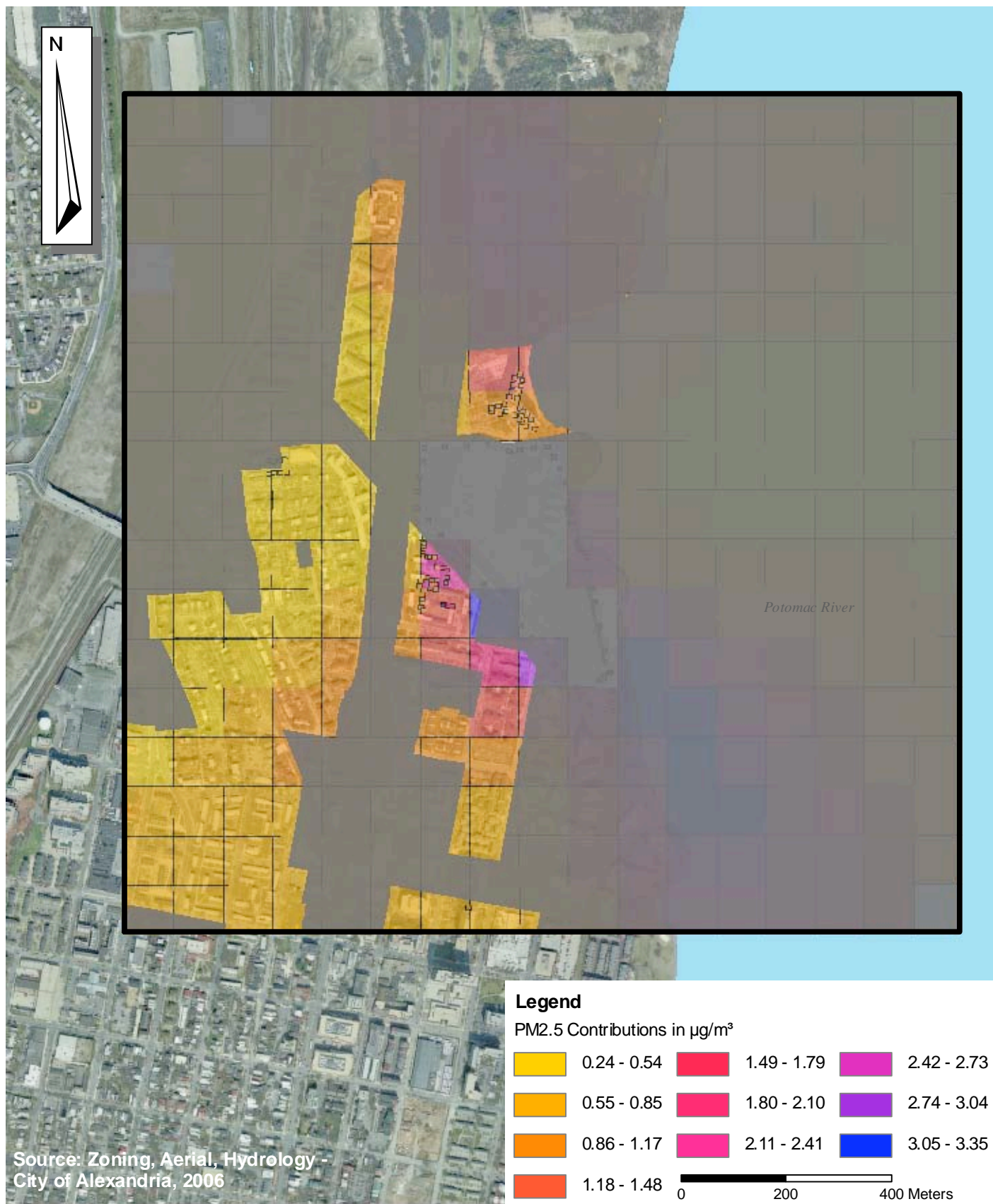


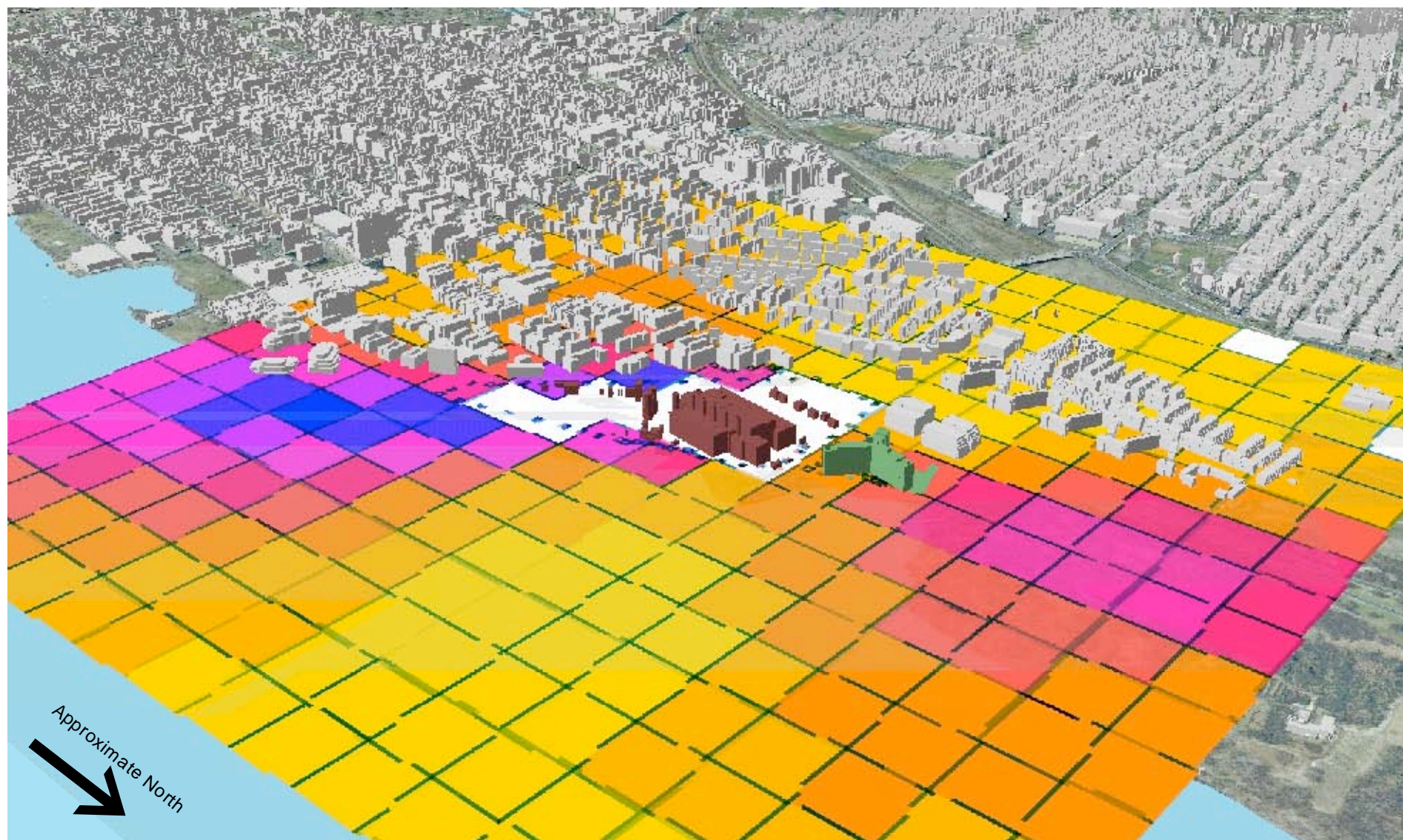












Legend

- PRGS
- Marina Towers

Source: Buildings, Aerial, Hydrology -
City of Alexandria, 2006

MEMORANDUM

To: Lora Werner, David Fowler, Debra Gable, and Ketna Mistry
cc: Bob Driscoll, Debra Bolton, and David Cramer
From: Laura Green
Subject: Follow up information and data on sulfur dioxide, particulate matter, and heavy metals
Date: August 15, 2007

Thank you again for our August 1, 2007 meeting in Alexandria VA. It was a pleasure to meet you, and to exchange ideas on several topics.

As I mentioned, there are various data sets that might be useful to you as you analyze and interpret the data from your ambient air sampling program. These data pertain to all three sets of pollutants included in your Exposure Investigation (EI). In particular, at your "Chemicals involved" website (<http://www.atsdr.cdc.gov/sites/mirant/chemicals.html>), you write:

ATSDR monitored for pollutants that are most likely to be emitted from the Mirant Plant and that are most likely to pose health concerns to the community. The pollutants monitored are sulfur dioxide (SO₂), select metals, and particulate matter.

Allow me please, on behalf of Mirant, to share the following relevant information with you.

Sulfur dioxide

As you have correctly noted, short-term (on the order of 5-minute) exposures to high concentrations of sulfur dioxide can cause respiratory problems for un-medicated exercising asthmatics (and, at very high concentrations, to anyone). As a result, since mid-April, 2007, Mirant has been collecting sulfur dioxide data at 5-minute intervals at its ambient air quality monitors very close to the plant. As you know, to date, none of the 5-minute sulfur dioxide samples from any of Mirant's six monitors targeted at the Potomac River Generating Station (PRGS) revealed concentrations as large as U.S. EPA's draft level of concern (600 – 1,000 parts per billion, ppb). Of the 193,483 valid measurements reported to date (from mid-April through August 9th), 93.6 % are smaller than 10 ppb, and 99.7 % are smaller than 100 ppb. Mirant plans to continue collecting these 5-minute data.

On the basis of extensive current data, then, sulfur dioxide concentrations in ambient air near the PRGS do not appear to pose a risk to public health.

Particulate matter (PM) — both total (TSP) and respirable (PM₁₀ and PM_{2.5})

As you may know, the City of Alexandria¹ has expressed a concern that the Potomac River Generating Station's (PRGS's) use of trona (sodium sesquicarbonate) in its pollution control systems may increase stack emissions (and hence local ambient air concentrations) of particulate matter (PM), especially fine particulate matter (PM_{2.5}). The City also noted some slight increases in average stack opacity readings during the summer of 2006 (when trona was in use) relative to the previous summer (when it was not). Based on these averages, the City hypothesizes, "given that . . . PM emissions tend to increase exponentially with opacity, and that Mirant PM testing data showed that ~80% of stack emissions was PM_{2.5}, it is very likely that PM_{2.5} emissions have increased with trona use."

As demonstrated below, in several respects, data from and near the PRGS do not support these hypotheses.

Prima facie, one might well expect that "more PM in = more PM out." As it happens, this is not the case for PRGS. This is because the PRGS units are equipped with two electrostatic precipitators (ESPs), in series — a "hot side" ESP, followed by a "cold side" ESP, prior to atmospheric release. (I know of no other power plants that have this feature). As shown below, these serial ESPs result in quite effective PM control, such that PM stack emissions in the presence of trona are no greater than, and sometimes less than, PM emissions when trona is not in use.

Moreover, under all circumstances, PM emissions from the PRGS are substantially less than the permit limit of 0.12 lb PM/MMBtu.

The relevant details are as follows.

In December 2006, PRGS unit 3 was tested when it was operating both without and with trona. Testing was for, among other things, filterable PM_{2.5}, PM₁₀, and total PM (that is, TSP; Conditional Method 040).²

¹ Via its letter of May 22, 2007, from John B. Britton (Counsel for the City of Alexandria) and Ignacio B. Pessoa (City Attorney, City of Alexandria) to Monica Harvey, VDEQ, "Re: Comments on Draft Permits," Attachment 2, page 2.

² The main body of the December 2006 Stack Test Report does not mention total PM measurements, but Appendix D to this Report provides test data on PM larger than 10 µm in diameter. These PM measurements essentially represent TSP.

PM concentrations were tested at three points:

1. The *inlet* to the first (hot-side) ESP;
2. The *outlet* from this first ESP (which also represents loading to the inlet to the second ESP); and
3. The *outlet* from the *second* (cold-side) ESP (which also represents emissions from the stack to the atmosphere).

As shown in Figure 1, and as one would expect, the particle loading entering the first ESP was substantial: on the order of 6 lb/MMBtu without trona, and 12 lb/MMBtu with trona.

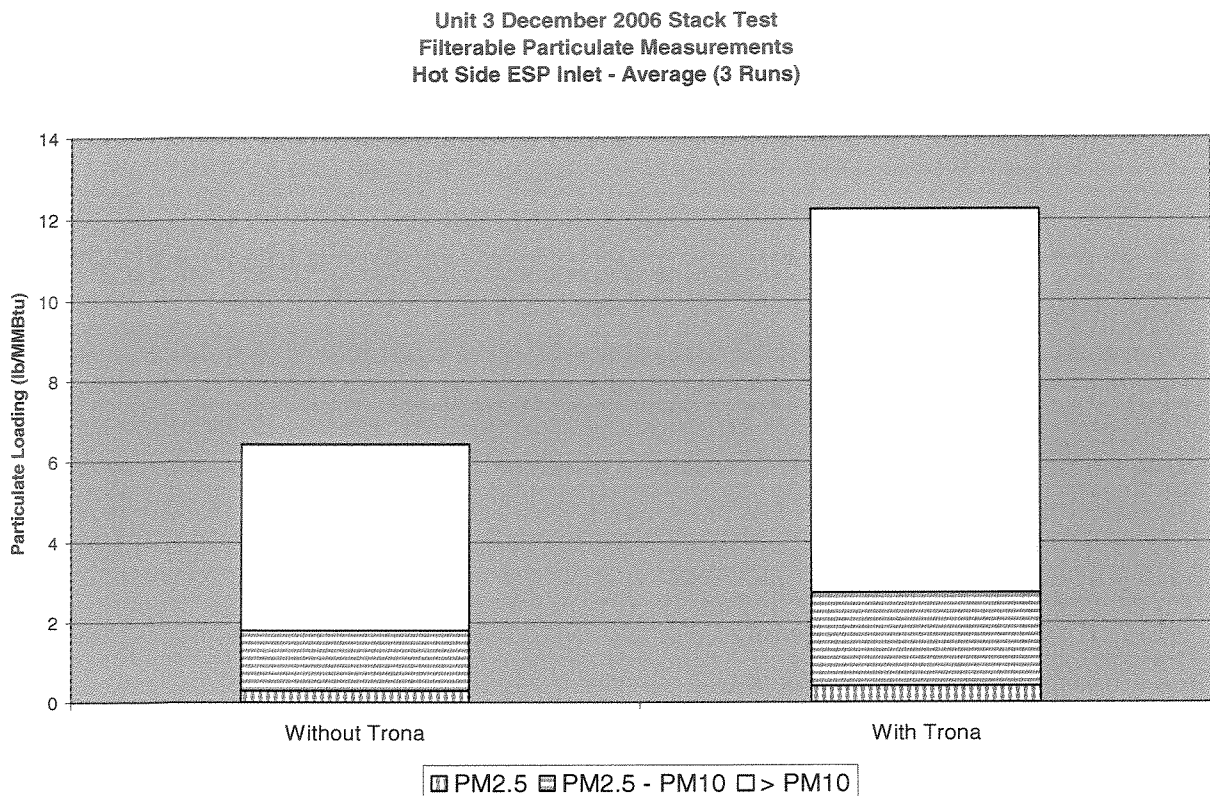


Figure 1

Figure 2 shows that the first ESP reduces this loading substantially, removing about 97% of the particles in both cases (so that about 0.15 and 0.3 lb/MMBtu entered the second ESP in the absence and in the presence of trona, respectively).

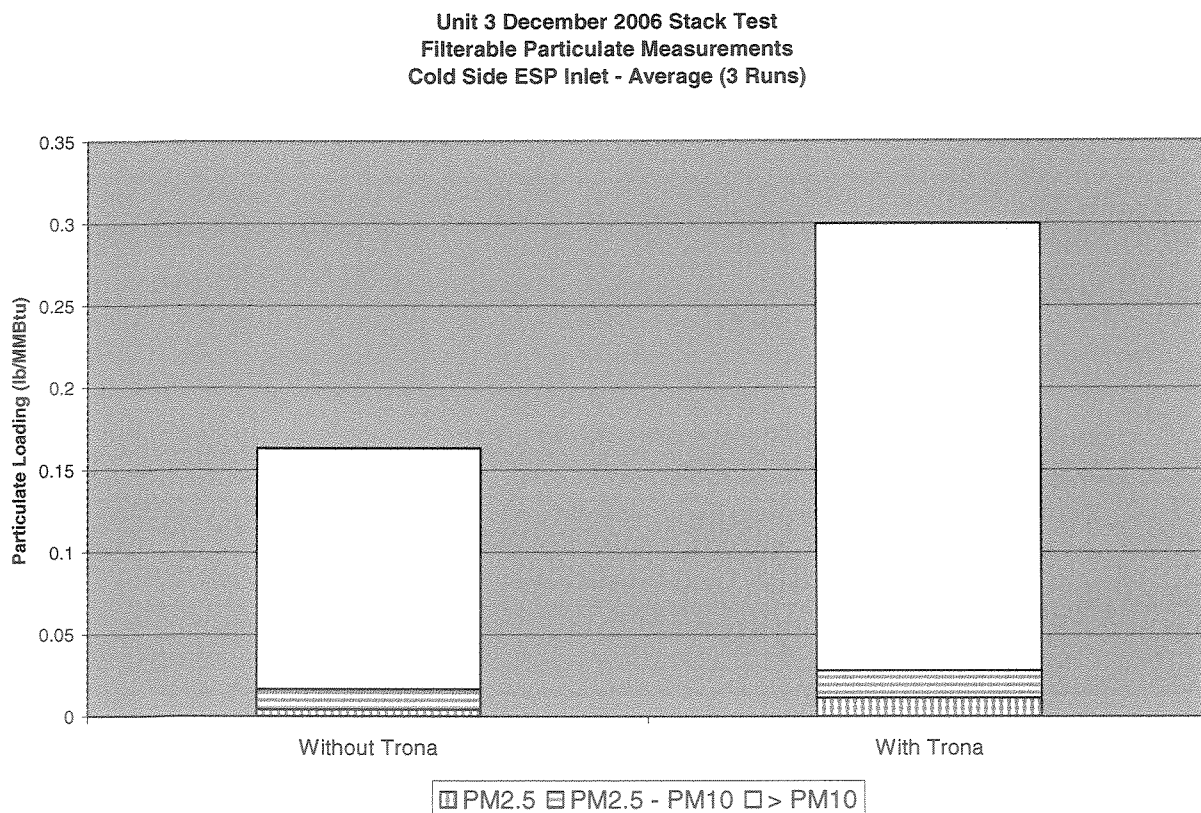


Figure 2

Interestingly, Figure 3 shows that the second ESP removes relatively more of the particles when trona is used than when it is not: the result is that PM *emissions* totaled only 0.007 lb/MMBtu *regardless* of the presence or absence of trona.

Please also note that, contrary to the City's hypothesis, non-respirable (that is, larger than 10 micron) particles dominate (in both cases), and that PM_{2.5} emissions are quite small (less than 0.001 lb/MMBtu).

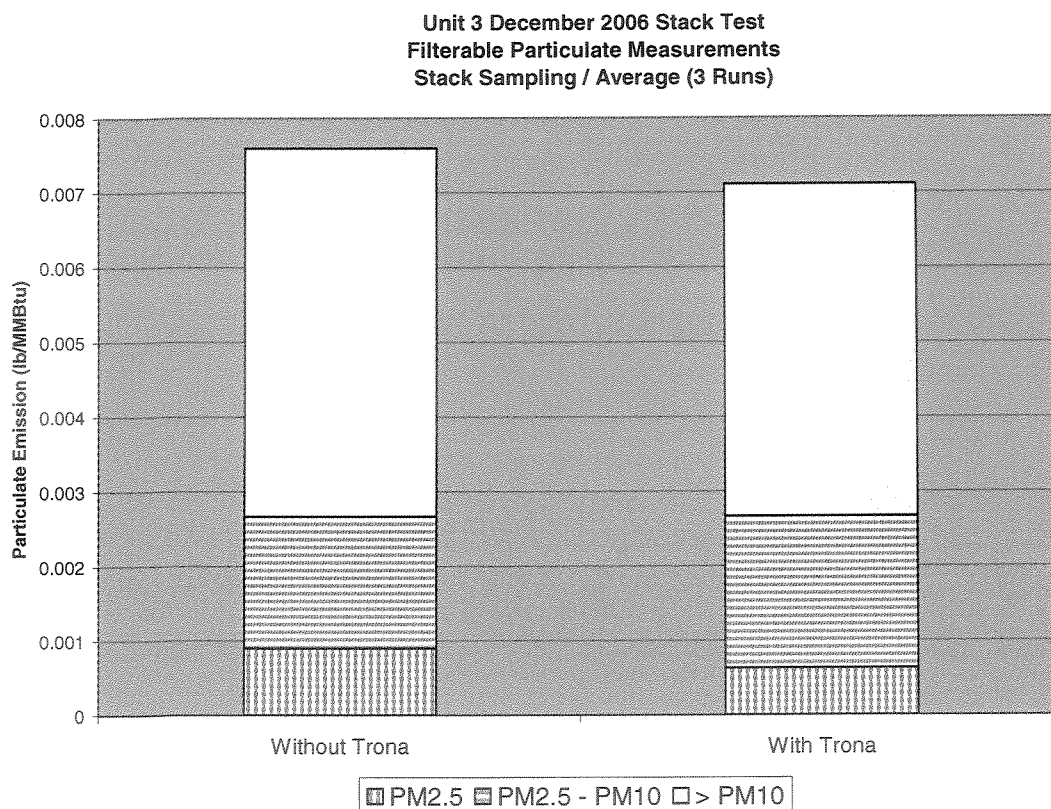


Figure 3

The following table summarizes the collection efficiencies of each ESP, and of the ESPs in series. The increased efficiency of the cold-side ESP in the presence of trona is notable.

Particulate Matter (PM) Collection Efficiencies Measured in Unit 3 Testing (December 2006)

| PM Fraction | Stack tests <i>without</i> Trona | | | Stack tests <i>with</i> Trona | | |
|-------------------|----------------------------------|---------------|-------------------------|-------------------------------|---------------|-------------------------|
| | Hot-side ESP | Cold-side ESP | Combined ESPs (Overall) | Hot-side ESP | Cold-side ESP | Combined ESPs (Overall) |
| PM _{2.5} | 98.8% | 74.9% | 99.7% | 97.6% | 94.2% | 99.9% |
| PM ₁₀ | 99.0% | 71.2% | 99.9% | 99.0% | 88.8% | 99.9% |
| TSP | 97.4% | 71.6% | 99.9% | 97.7% | 96.0% | 99.9% |

Testing of PM₁₀ emissions undertaken a year earlier (December 2005), on unit 1, also showed that use of trona did not increase PM₁₀ stack emissions, and even significantly reduced such emissions, relative to the “no trona” case.

I have also examined whether opacity readings, in the typical range of 3% to 7%, correlate with PM emissions. As shown in Figure 4, they do not.

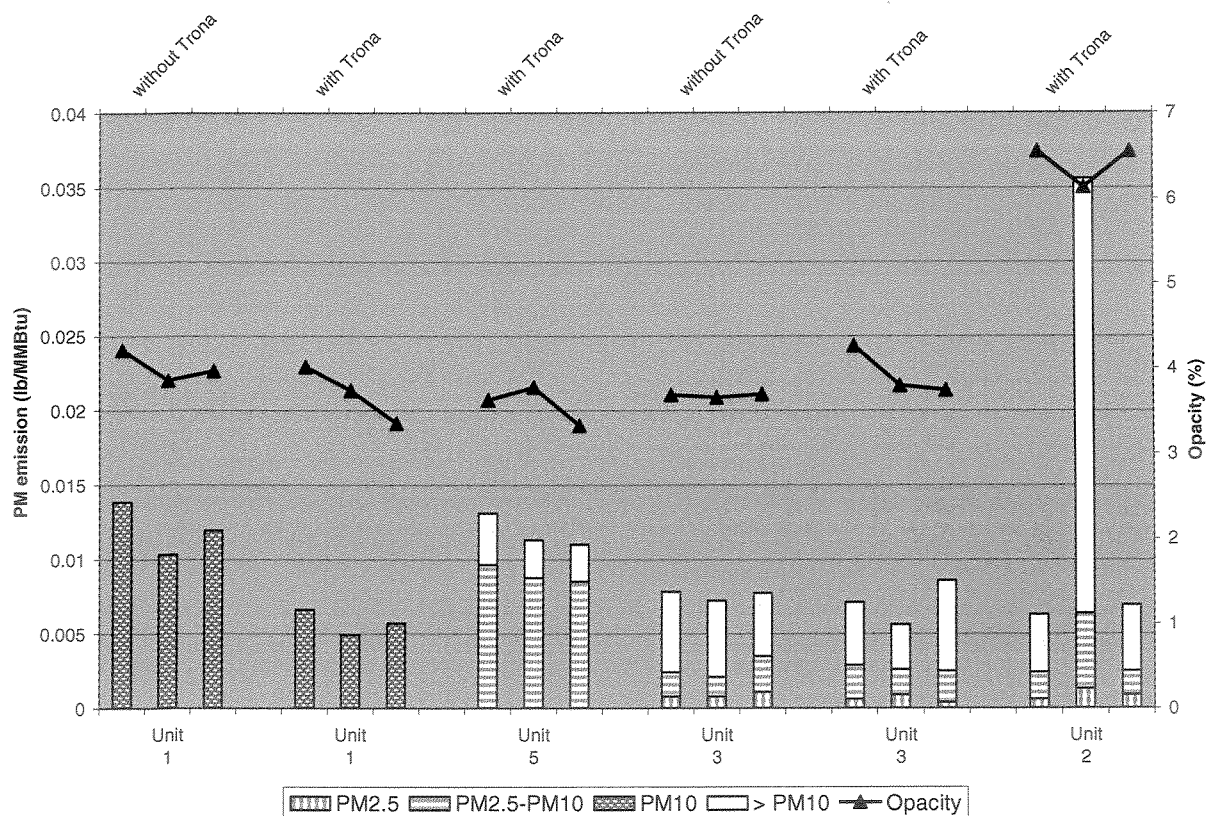


Figure 4

As depicted in Figure 4, total PM emissions (that is, both larger and smaller than 10 microns in mass mean aerodynamic diameter) were monitored during four of these sets of tests: for the two sets of tests performed on unit 1, only PM₁₀ data are available. Regardless, whether one focuses on total PM or respirable PM, variations in opacity do not predict variations in PM emissions.

Of course, in the extreme, very low (or very high) opacity readings correlate with very small (or very large) concentrations of PM, but variations between 3% and 7%, at least in this setting, do not. More generally, opacity depends on several factors other than total PM mass concentrations, including particle size distributions and specific qualities of particles that affect light scattering/reflection (see, for example, EPA, 2000, *Current Knowledge of Particulate Matter (PM) Continuous Emission Monitoring*. Available at: <http://www.epa.gov/ttn/emc/cem/pmcmknowfinalrep.pdf>).

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Finally, Mirant's ambient air PM_{2.5} monitors, targeted at "worst-case points" near the PRGS, have shown 24-hour average concentrations of only 13 µg/m³. In only one instance has *any* PRGS PM_{2.5} monitor registered a 24-hour average value larger than the new NAAQS of 35 µg/m³ (this was a 24-hr. value on May 26, 2007, which was 36.2 µg/m³), but this concentration was recorded when southerly winds were blowing *from* the monitor *to* the facility, so were not reflective of contributions from the PRGS.

Overall, then, stack test data, opacity data, and ambient air monitoring data indicate that the City's concerns with regard to the PRGS and particulate matter emissions and/or impacts are unsupported.

Metals on PM

As we discussed, and as you know, all samples of TSP taken anywhere in the world will show detectable concentrations of most of the metals you are seeking in your study. This is because TSP metals derive from natural crustal sources, from re-suspended dust from roads, fields, and other "area" sources, and from emissions from mobile and stationary point sources.

Importantly, stack-test and fly ash-test data from the PRGS indicate that none of the metals sought in your Exposure Investigation are emitted to ambient air at toxicologically significant rates.

The relevant details are these.

As you know, samples of PRGS fly ash — generated both with and without the use of trona — have been analyzed for heavy metals and other inorganic constituents. Only trace concentrations of many metals were found, and, as expected, mercury was not detected in any samples, regardless of trona use (<http://www.eh.doe.gov/nepa/seas/sea-04.pdf>). Given the very low emission rates of total PM from the PRGS (as described above), and given the tiny proportions of emitted PM that are heavy metals (as opposed to sulfates, nitrates, organic aerosols, silica, and alumina), the hypothesis that PRGS's emissions *per se* could lead to toxicologically significant concentrations of these metals in ambient air is unsupported.

Moreover, as we also discussed, since your metals data will be from TSP, not from respirable PM, it will be important (i) to compare your results to TSP-metals data from control sites, and (ii) to refrain from interpreting the data by means of comparisons to "cancer reference" concentrations, since the latter apply to respirable PM, not to TSP (and since metal contents of the latter cannot be used to extrapolate to metal contents of the former).

To assist you with your comparisons, we have compiled data on TSP-metals concentrations in other areas of the U.S. (restricted to East of the Mississippi River, since soil compositions differ in the West). The results are as follows, and our spreadsheet is attached for your use.

| Metals that ATSDR seeks in ambient air <i>via</i> its EI near the PRGS | |
|---|--|
| Metal | Range of 2006 annual average concentrations at Eastern/mid-Western sites ^(A) |
| Antimony | 0.001 – 0.003 $\mu\text{g}/\text{m}^3$ |
| Arsenic | 0.00054 – 0.006 $\mu\text{g}/\text{m}^3$ |
| Beryllium | 0.000031 – 0.00041 $\mu\text{g}/\text{m}^3$ |
| Cadmium | 0.0001 – 0.0028 $\mu\text{g}/\text{m}^3$ |
| Chromium, total | 0.001 – 0.016 $\mu\text{g}/\text{m}^3$ ^(B) |
| Cobalt | 0.00015 – 0.0010 $\mu\text{g}/\text{m}^3$ |
| Lead | 0.002 – 0.756 $\mu\text{g}/\text{m}^3$ |
| Manganese | 0.004 – 2.2 $\mu\text{g}/\text{m}^3$ |
| Mercury | — ^(C) |
| Nickel | 0.0007 – 0.067 $\mu\text{g}/\text{m}^3$ |
| Selenium | — ^(D) |

^A Minimum and maximum of annual average atmospheric mass concentrations measured in TSP samples collected at U.S. EPA monitoring sites in states east of the Mississippi River. Data include results from monitors with at least 50% of concentrations measured above the detection limit, and with non-zero reported annual averages. Data downloaded from the U.S. EPA AirData Annual Summary Table Query webpage:
http://www.epa.gov/aqspubl1/annual_summary.html.

^B Measured concentrations are for **total** chromium, not hexavalent chromium. Per SCAQMD (2000), only some 2% of total chromium in ambient air PM is in the form of CrVI.

^C Only 10 TSP mercury concentrations above the detection limit were measured in 116 samples at 10 monitoring locations. No monitoring locations had greater than 50% of concentrations measured above the detection limit.

^D No non-zero annual average values for TSP selenium were reported in 2006 for monitors east of the Mississippi River.

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Ketna Mistry
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Based on the ubiquity of many of these metals, especially of arsenic (As), cadmium (Cd), and chromium (Cr), you can expect to find concentrations of two or three of these metals that, at first glance, might appear to exceed “levels of concern,” based on theoretical cancer risk estimates. Of course, as noted above, since you are not collecting respirable metals data, no such theoretical cancer risk estimates would be appropriate. Also, as noted above, the emissions data and fly ash data show that PRGS is not a significant atmospheric source of these metals in either respirable or non-respirable particulate emissions. To the extent that your “Chemicals involved” website (<http://www.atsdr.cdc.gov/sites/mirant/chemicals.html>) suggests otherwise, it is not accurate.

Moreover, only a tiny fraction of the Cr that you will detect will be present as Cr VI (the only form known to cause cancer, given sufficiently high exposures). As you know, Cr is present in very small concentrations (typically nanograms per cubic meter, ng/m^3) in ambient air due to both natural and anthropogenic sources. Airborne crustal dust contains Cr primarily from Cr III-based ores (NAS, 1974; Lantzy and MacKenzie, 1979). Data reported by the South Coast Air Quality Management District (SCAQMD) indicate that hexavalent chromium constitutes a small fraction of the total chromium in ambient air, even near cooling towers that use chromates as anti-scaling agents, let alone elsewhere. According to ambient air samples from a major air quality study focused on hazardous air pollutants (SCAQMD, 2000), hexavalent chromium makes up only 1.0-3.3% of the total chromium in ambient air, even at expected Cr VI “hot spots,” with an average of 2% and an absolute concentration of 0.2 ng/m^3 of Cr VI.



I hope that this information is useful to you as you move forward with your study and reports. Please call or write with questions or concerns, or if I can further assist.

Thank you, and best regards.

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ENSR

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February 15, 2008

David Cramer,
Director - Environmental Policy & Regulation
Mirant - Mid-Atlantic
8301 Professional Place, Suite 230
Landover, MD 20785

Subject: ENSR Comments on Earth Tech Report Entitled "Evaluation of Health Effects From Increased PM_{2.5} To Residents Near the Potomac River Generating Station (PRGS)"

Dear Mr. Cramer,

ENSR has the following comments on this report dated January, 2008:

1) The report calculates "additional premature mortalities" and "additional health effects" due to the two stack permit. The report does this through analysis of PRGS's incremental impacts above a baseline concentration of 34.1 ug/m³. The report assumes that the existing plant's impacts are contained within the baseline concentration. The report also assumes that PM_{2.5} emissions = 0.055 lb/MMBtu (0.03 lb/MMBtu primary emissions + 0.025 lb/MMBtu secondary emissions contributed by 7% of the SO₂ rate of 0.35 lb/MMBtu).

The report makes a **fatal error** by not considering the net impacts of the PRGS' PM_{2.5} emissions. Net impacts would be determined by modeling the existing facility (the 2002 - 2004 period or the June 1, 2007 permit) and modeling the two stack permit and subtracting out the impacts from the 2002 - 2004 or the June 1, 2007 permit. As we have seen in the recent SO₂ isopleth maps we produced, there is a dramatic improvement in impacts between the 2002-2004 period and the two stack permit and a small but definable improvement between the two stack permit and the June 1, 2007 permit. The PM emission limit used to be 0.12 lb/MMBtu (2002 - 2004 period). More recently, a PM₁₀ value of 0.055 lb/MMBtu has been used. In the two stack permit, PM₁₀ emissions are limited to 0.03 lb/MMBtu. Therefore, assuming similar reductions in PM_{2.5} from 2002-2004 to now, the impacts due to the two stack permit would definitely be lower than the 2002-2004 period and lower than the June 1, 2007 permit.

Overall, rather than an increase in premature mortalities and additional health effects, the two stack permit produces a decrease in these factors.

2) The assumption that 0.025 lb/MMBtu secondary PM_{2.5} emissions are formed immediately upon exiting the stack has no basis and goes against recommendations to model only primary PM_{2.5} emissions for near-field application for new major sources with less than 250 ton per year increase of PM_{2.5} precursors SO₂ or NO_x (e.g., State of New Jersey Memorandum from John Preczewski to BOP, BPP and BTS Supervisors; Subject: Revised Interim PM_{2.5} Permitting and Modeling Procedures, May 11, 2007, pp. 2 - 5). For the two stack permit there is no proposed SO₂ or NO_x increase.

3) The assumption that PM_{2.5} emissions are 0.03 lb/MMBtu is incorrect. Stack testing performed during 2005 - 2007 indicates that PM_{2.5} emissions are 0.016 lb/MMBtu.

4) The report calculates additional mortalities and additional health effects for two scenarios: a worst-case 24-hour and annual average scenario. The worst-case 24-hour scenario assumes that highest 24-hour PM_{2.5} impacts predicted at each receptor (e.g., 42.83 ug/m³ on top of Marina Towers) remain at

that concentration for every day of the year. This is impossible. Based on a review of Figures 4 and 5, the annual average concentration on top of Marina Towers is 1.18 - 1.48 $\mu\text{g}/\text{m}^3$. This range of concentrations is only 2.8% - 3.5% of the maximum 24-hour concentration.

5) The report indicates that the modeled maximum 24-hour impact from the two stack permit is 42.8 $\mu\text{g}/\text{m}^3$. One year of $\text{PM}_{2.5}$ monitoring of existing operations at locations of highest predicted impact from Alexandria's modeling (top of Marina Towers and along the SE fenceline) indicates that PRGS has a maximum 24-hour impact of about 1 $\mu\text{g}/\text{m}^3$ on top of Marina Towers and about 1 - 4 $\mu\text{g}/\text{m}^3$ at the SE fenceline. The maximum observed impacts from PRGS occur only a couple of times per year (during strong winds) when $\text{PM}_{2.5}$ background concentrations are on the order of 5 - 15 $\mu\text{g}/\text{m}^3$. Otherwise, little or no impacts from PRGS have been observed. The two stack permit will result in slightly lower $\text{PM}_{2.5}$ impacts on top of Marina Towers than existing operations because flue gases will be merged, producing higher plume rise. Therefore, maximum $\text{PM}_{2.5}$ impacts will remain on the order of 1 $\mu\text{g}/\text{m}^3$ at that location. Maximum impacts at ground level should remain at the 1-4 $\mu\text{g}/\text{m}^3$ level as well. The modeled impact of 42.8 $\mu\text{g}/\text{m}^3$ is an impossibility. Use of accurate emissions data in the model (i.e., a $\text{PM}_{2.5}$ emission rate of 0.016 lb/MMBtu, instead of 0.055 lb/MMBtu) would lower the predicted impacts by 71% to 12.8 $\mu\text{g}/\text{m}^3$. This value is still higher than expected but at least closer to observed $\text{PM}_{2.5}$ impacts.

6) Total $\text{PM}_{2.5}$ concentrations were predicted to be 76.9 $\mu\text{g}/\text{m}^3$ for a 24-hour period. This concentration was arrived at by adding the 42.8 $\mu\text{g}/\text{m}^3$ predicted concentration to a 98th percentile background concentration of 34.1 $\mu\text{g}/\text{m}^3$. The maximum observed $\text{PM}_{2.5}$ concentrations at the two locations where highest impacts were predicted by the model (top of marina Towers and at the SE fenceline) were 43.5 $\mu\text{g}/\text{m}^3$ at Marina Towers and 49.6 $\mu\text{g}/\text{m}^3$ at the SE fenceline (TEOM). These concentrations (in fact all high background concentrations) were associated with several days of light southerly winds that advected dirtier air into the region from the south and southwest. On these "high background" days, $\text{PM}_{2.5}$ concentrations are high at all monitors in the region. In fact, on high background days, the Marina Towers and SE fenceline monitors do not record the highest $\text{PM}_{2.5}$ concentrations in the region. It is impossible that a total concentration of 76.9 $\mu\text{g}/\text{m}^3$ could be recorded in the vicinity of PRGS.

Summary:

The Earth Tech report is fatally flawed because it does not consider the net change in impacts brought about by the two stack permit. By not considering the net change in impacts, the report is assuming that the present facility has no impacts above background. A modeled net change in $\text{PM}_{2.5}$ emissions (using either permitted or actual emissions) would indicate a net decrease in $\text{PM}_{2.5}$ impacts, thus improving the air quality. The report also contains other errors, including overestimation of $\text{PM}_{2.5}$ emissions, including secondary $\text{PM}_{2.5}$ emissions and assuming that a worst-case 24-hour period lasts for 365 days.

Sincerely yours,



David M. Shea, CCM
Senior Program Manager



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Journal Article

Evaluating Particulate Emissions from Jet Engines: Analysis of Chemical and Physical Characteristics and Potential Impacts on Coastal Environments and Human Health

| | |
|-------------|--|
| Journal | Transportation Research Record |
| Publisher | Transportation Research Board of the National Academic |
| ISSN | 0361-1981 |
| Issue | Volume 1517 / 1996 |
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| Online Date | Thursday, January 18, 2007 |

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Abstract

The results of this study suggest that the range of size of particulate emissions from some jet engines clusters below 1.5 μm and that the emissions contain heavy metals. Therefore, jet exhaust particulates (JEPs) have the potential to adversely affect both the environment and human health. Little is known about the particulate component of jet engine emissions. Baseline physical and chemical data on JEPs were obtained to evaluate their potential effects on the environment. Particles collected from the exhaust stream of two types of jet engines were examined using scanning electron microscopy. Analysis indicated that 100 percent of the particles collected were below 1.5 μm in size. Particles in this size range can penetrate to the alveoli of human lungs. Chemical analyses of jet engine exhaust were conducted in an attempt to identify chemical fingerprints that would distinguish aviation emissions in the environment from other anthropogenic emissions. Certain heavy metals, especially vanadium, were found in jet exhaust and may be useful chemical fingerprints. Analysis of JP-5 fuel standards revealed a suite of alkylbenzene hydrocarbons, which may also aid in fingerprinting aviation emissions. Sediment samples taken at coastal wetlands near airports indicated the presence of the same heavy metals as those found in jet

exhaust samples. Field sites exposed to higher volumes of air traffic contained higher levels of sediment heavy metals, supporting the hypothesis that aerial deposition of heavy metals is occurring in areas near some airports.

References

References secured to subscribers.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 87

[AMS-FRL-7561-7]

RIN 2060-AK01

Control of Air Pollution From Aircraft and Aircraft Engines; Emission Standards and Test Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, we are proposing to amend the existing United States regulations governing the exhaust emissions from new commercial aircraft gas turbine engines. Under the authority of section 231 of the Clean Air Act (CAA), the Environmental Protection Agency (EPA) is proposing new emission standards for oxides of nitrogen (NO_x) for newly certified commercial aircraft gas turbine engines with rated thrust greater than 26.7 kilonewtons (kN). This action proposes to adopt standards equivalent to the latest (effective in 2004) NO_x standards of the United Nations International Civil Aviation Organization (ICAO), and thereby bring the United States emission standards into alignment with the internationally adopted standards. In addition, today's action also would amend the test procedures for gaseous exhaust emissions to correspond to recent amendments to the ICAO test procedures for these emissions.

After December 31, 2003, the proposed NO_x standards would apply to newly certified gas turbine engines—those engines designed and certified after the effective date of the proposed regulations (for purposes of this action, the date of manufacture of the first individual production model means the date of type certification). Since the proposed NO_x standards would apply to only newly certified gas turbine engines, newly manufactured engines (those engines built after the effective date of the proposed regulations) would not have to meet these standards. Moreover, all engines currently being built would not have to comply with the NO_x emission standards that EPA is adopting today.

Today's proposed amendments to the emission test procedures are those recommended by ICAO and are widely used by the aircraft engine industry. Thus, today's action would establish consistency between U.S. and international standards, requirements, and test procedures. Since aircraft and aircraft engines are international

commodities, there is significant commercial benefit to consistency between U.S. and international emission standards and control program requirements. In addition, today's action ensures that domestic commercial aircraft would meet the current international standards, and thus, the public can be assured they are receiving the air quality benefits of the international standards.

DATES: *Comments:* EPA requests comments on the proposed rulemaking by December 15, 2003. More information about commenting on this action may be found under Public Participation in the **SUPPLEMENTARY INFORMATION** section and section I.C.

Hearing: We will hold a public hearing on November 13, 2003. The hearing will start at 10 a.m. local time and continue until everyone has had a chance to speak. If you want to testify at the hearing, notify the contact person listed below at least ten days before the hearing.

ADDRESSES: *Comments:* Comments may be submitted by mail to: Air Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. OAR 2002-0030. Comments may also be submitted electronically, by facsimile, or through hand delivery/courier. Follow the detailed instructions as provided in section I.C. of the **SUPPLEMENTARY INFORMATION** section.

Hearing: The public hearing will be held at the Environmental Protection Agency, EPA East Building, Room Number 1153, 1201 Constitution Avenue, NW., Washington, DC 20004, Telephone: (202) 564-1682. See section VIII for more information about public hearings.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Manning, U.S. EPA, Office of Transportation and Air Quality, Assessment and Standards Division, 2000 Traverwood, Ann Arbor, MI 48105. Telephone (734) 214-4832; Fax: (734) 214-4816, E-mail: manning.bryan@epa.gov.

SUPPLEMENTARY INFORMATION:

Outline of This Preamble

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I. General Information

A. Regulated Entities

Entities potentially regulated by this action are those that manufacture and sell commercial aircraft engines and aircraft in the United States, and the owners/operators of such aircraft (and accompanying engines) in the United States. Regulated categories include:

| Category | NAICS ^a codes | SIC codes ^b | Examples of potentially affected entities |
|----------------|--------------------------|------------------------|--|
| Industry | 336412 | 3724 | Manufacturers of new aircraft engines. |
| Industry | 336411 | 3721 | Manufacturers of new aircraft. |
| Industry | 481 | 4512 | Scheduled air carriers, passenger and freight. |

^a North American Industry Classification System (NAICS).

^b Standard Industrial Classification (SIC) system code.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your activities are regulated by this action, you should carefully examine the applicability criteria in 40 CFR 87.20. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OAR 2002-0030. The official public docket is the collection of materials that is available for public viewing at the Air Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room and the Air Docket is (202) 566-1742. You may be charged a reasonable fee for photocopying docket materials, as provided in 40 CFR part 2.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/>

to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as confidential business information (CBI) and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or

other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact

information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

a. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources," "Dockets," and "EPA Dockets." Once in the system, select "search," and then key in Docket ID No. OAR 2002-0030. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

b. *E-mail.* Comments may be sent by electronic mail (e-mail) to aircraft@epa.gov, Attention Docket ID No. OAR 2002-0030. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

c. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: Air Docket, Environmental Protection

Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. OAR 2002-0030.

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20004, Attention Docket ID No. OAR 2002-0030. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1.

4. *By Facsimile.* Fax your comments to: (202) 566-1741, Attention Docket ID. No. OAR 2002-0030.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline identified.

8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Introduction

A. Brief History of EPA's Regulation of Aircraft Engine Emissions

Section 231(a)(2)(A) of the Clean Air Act (CAA) directs the EPA Administrator to "issue proposed emission standards applicable to the emission of any air pollutant from any class or classes of aircraft or aircraft engines which in his judgment causes, or contributes to, air pollution which may reasonably be anticipated to endanger public health or welfare" (42 U.S.C. 7571(a)(2)(A)). Under this authority EPA has conducted several rulemakings since 1973 establishing emission standards and related requirements for several classes (commercial and general aviation engines) of aircraft and aircraft engines. Most recently, in 1997 EPA promulgated NO_x emission standards for newly manufactured gas turbine engines (those engines built after the effective date of the regulations or already certified engines) and for newly certified gas turbine engines (those engines designed and certified after the effective date of the regulations¹).² In addition, EPA promulgated a carbon monoxide (CO) emission standard for newly manufactured gas turbine engines in this same 1997 rulemaking. At the time, the 1997 rulemaking established consistency between the U.S. and international standards. (See 40 CFR part 87 for a description of EPA's aircraft engine emission control requirements and 14 CFR part 34 for the Secretary of Transportation's regulations for ensuring compliance with these standards in accordance with section 232 of the Clean Air Act.)

¹ Throughout this notice, the date of manufacture of the first individual production model means the date of type certification.

² U.S. EPA, "Control of Air Pollution from Aircraft and Aircraft Engines; Emission Standards and Test Procedures;" Final Rule, 62 FR 25356, May 8, 1997.

B. Interaction With the International Community

Since publication of the initial standards in 1973, EPA, together with the Federal Aviation Administration (FAA), has worked with the International Civil Aviation Organization (ICAO) on the development of international aircraft engine emission standards. ICAO was established in 1944 by the United Nations (by the Convention on International Civil Aviation, the "Chicago Convention") " * * * in order that international civil aviation may be developed in a safe and orderly manner and that international air transport services may be established on the basis of equality of opportunity and operated soundly and economically." ³ ICAO's responsibilities include developing aircraft technical and operating standards, recommending practices, and generally fostering the growth of international civil aviation.

In 1972 at the United Nations Conference on the Human Environment, ICAO's position on the human environment was developed to be the following: "[i]n fulfilling this role ICAO is conscious of the adverse environmental impact that may be related to aircraft activity and its responsibility and that of its member States to achieve maximum compatibility between the safe and orderly development of civil aviation and the quality of the human environment." Also, in 1972 ICAO established the position to continue " * * * with the assistance and cooperation of other bodies of the Organization and other international organizations * * * the work related to the development of Standards, Recommended Practices and Procedures and/or guidance material dealing with the quality of the human environment * * *," ⁴

The United States is one of 188 participating member States of ICAO.⁵ Under the basic ICAO treaty established in 1944 (the Chicago Convention), a participating nation which elects not to adopt the ICAO standards must provide a written explanation to ICAO

describing why a given standard is impractical to comply with or not in their national interest.⁶ ICAO has no punitive powers for states that elect not to adopt ICAO standards. ICAO standards require States to provide written notification and failure to provide such notification could have negative consequences as detailed below.

If a Contracting State files a written notification indicating that it does not meet ICAO standards, other Contracting States are absolved of their obligations to "recognize as valid" the certificate of airworthiness issued by that Contracting State, since that certificate will not have been issued under standards "equal to or above" ICAO standards. In other words, other Contracting States do not have to allow aircraft belonging to that Contracting State to travel through their airspace.⁷ Further, if it fails to file a written notification, it will be in default of its obligations, and risks mandatory exclusion of its aircraft from the airspace of other Contracting States and the loss of its voting power in the Assembly and Council.⁸

The ICAO Council's Committee on Aviation Environmental Protection (CAEP) undertakes ICAO's technical work in the environmental field. The CAEP is responsible for evaluating, researching, and recommending measures to the ICAO Council that address the environmental impact of international civil aviation. CAEP is composed of various Study Groups, Work Groups, Committees and other contributing memberships that include atmospheric, economic, aviation, environmental, and other professionals committed to ICAO's previously stated

position regarding aviation and the environment. At CAEP meetings, the United States is represented by the FAA, which plays an active role at these meetings (see section V for further discussion of FAA's role). EPA is a principal participant in the development of U.S. policy in ICAO/CAEP and other international venues. (EPA assists and technically advises FAA on aviation emissions matters.) If the ICAO Council adopts a CAEP proposal to adopt a new environmental standard, it then becomes part of the ICAO standards and recommended practices (Annex 16 to the Chicago Convention).⁹

On June 30, 1981, the ICAO Council adopted its first international standards and recommended practices covering aircraft engine emissions.¹⁰ These standards limit aircraft engine emissions of NO_x, CO, and hydrocarbons (HC), in relation to other engine performance parameters, and are commonly known as stringency standards. On March 24, 1993, the ICAO Council approved a proposal adopted at the second meeting of the CAEP (CAEP/2) to tighten the original NO_x standard by 20 percent and amend the test procedures. At the next CAEP meeting (CAEP/3) in December 1995, the CAEP recommended a further tightening of 16 percent and additional test procedure amendments, but on March 20, 1997 the ICAO Council rejected this stringency proposal and approved only the test procedure amendments. At its next meeting (CAEP/4) in April 1998, the CAEP adopted a similar 16 percent NO_x reduction proposal, which the ICAO Council approved on February 26, 1999.¹¹ The CAEP/4 16 percent NO_x reduction standard applies to new engine designs certified after December 31, 2003 (applies only to newly certified engines).¹²

As discussed earlier, in 1997 EPA amended its regulations to adopt the

⁶ Text of Article 38 of Chicago Convention: Any State which finds it impracticable to comply in all respects with any such international standard or procedure, or to bring its own regulations or practices into full accord with any international standard or procedure after amendment of the latter, or which deems it necessary to adopt regulations or practices differing in any particular respect from those established by an international standard, shall give immediate notification to the International Civil Aviation Organization of the differences between its own practice and that established by the international standard. * * * In any such case, the Council shall make immediate notification to all other states of the difference which exists between one or more features of an international standard and the corresponding national practice of that State.

⁷ Text of Article 33 of Chicago Convention: Certificates of airworthiness and certificates of competency and licenses issued or rendered valid by the contracting State in which the aircraft is registered, shall be recognized as valid by the other contracting States, provided that the requirements under which such certificates or licenses were issued or rendered valid are equal to or above the minimum standards which may be established from time to time pursuant to this Convention.

⁸ Articles 87 and 88 of Chicago Convention.

⁹ ICAO, "Aircraft Engine Emissions," International Standards and Recommended Practices, Environmental Protection, Annex 16, Volume II, Second Edition, July 1993. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

¹⁰ ICAO, Foreword of "Aircraft Engine Emissions," International Standards and Recommended Practices, Environmental Protection, Annex 16, Volume II, Second Edition, July 1993. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

¹¹ International Civil Aviation Organization (ICAO), Aircraft Engine Emissions, Annex 16, Volume II, Second Edition, July 1993, Amendment 4 effective on July 19, 1999. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

¹² These NO_x standards will be interchangeably be referred to as the 1998 CAEP/4 standards and the 1999 ICAO standards throughout this notice.

³ ICAO, "Convention on International Civil Aviation," Sixth Edition, Document 7300/6, 1980. Copies of this document can be obtained from the ICAO Web site located at <http://www.icao.int>.

⁴ International Civil Aviation Organization (ICAO), Foreword of "Aircraft Engine Emissions," International Standards and Recommended Practices, Environmental Protection, Annex 16, Volume II, Second Edition, July 1993. Copies of this document can be obtained from the ICAO Web site located at <http://www.icao.int>.

⁵ As of June 20, 2002 there were 188 Contracting States according to the ICAO Web site located at <http://www.icao.int>.

1981 ICAO NO_x and CO emission standards, as well as the NO_x emission standards and test procedures revised by ICAO in 1993. As discussed above, the U.S. has an obligation under the Convention on International Civil Aviation to notify ICAO regarding differences between U.S. standards and ICAO standards, and to provide notification on the date by which the program requirements will be consistent. In response to the recent actions by ICAO and for the reasons discussed below, EPA proposes to adopt standards equivalent to ICAO's 1999 amendment to the NO_x emission standard, the test procedure changes approved by ICAO in 1997, and other technical amendments to further align EPA and ICAO requirements.

C. EPA's Responsibilities Under the Clean Air Act

As discussed earlier, section 231 of the CAA directs EPA, from time to time, to propose aircraft engine emission standards for any air pollutant that could reasonably endanger public health and welfare. In addition, EPA is required to ensure such standards' effective dates permit the development of necessary technology, giving appropriate consideration to compliance cost. Also, EPA must consult with the FAA concerning aircraft safety before proposing or promulgating emission standards. (See section V of today's proposal for further discussion of EPA's coordination with FAA and FAA's responsibilities under the CAA.)

In addition, section 233 of the CAA vests authority to implement emission standards for aircraft engines only in EPA.¹³ States are preempted from taking independent action. Thus, while many states are implementing control programs to reduce mobile source emissions, EPA has the authority to establish an emission control program for aircraft engines.

III. Environmental Need for Control

As mentioned above, section 231(a)(2)(A) of the CAA authorizes the EPA Administrator to, from time to time, revisit emission standards for aircraft engine emissions " * * * which in his judgment causes, or contributes to air pollution which may * * * endanger public health or welfare." In judging the need for the NO_x standard promulgated in today's action, the

Administrator has determined (1) That the public health and welfare is endangered in several air quality regions by violation of the National Ambient Air Quality Standards (NAAQS) for ozone (NO_x contributes to the formation of ozone); and (2) that airports and aircraft are now or are projected to be, increasing sources of emissions of NO_x in some of the air quality control regions in which the NAAQS are being violated.

Nationwide, aircraft account for about 1 percent of the NO_x emissions from mobile sources.¹⁴ Commercial aircraft emissions contribute from 74 to 99 percent of the NO_x aircraft emissions in the U.S. (Aircraft emissions sources include aircraft types used for public, private, and military purposes as follows: commercial aircraft, air taxis, general aviation, and military aircraft.¹⁵ The current nationwide aircraft emission estimates have limitations for military aircraft emissions. Therefore, the estimated range of commercial aircraft's emissions contribution to nationwide aircraft NO_x described above is reflective of earlier and current estimates for military aircraft emissions).

Commercial aircraft emissions are projected to be a growing segment of the transportation sector's emission inventory. This growth in commercial aircraft emissions is expected to occur at a time when other significant mobile and stationary sources are drastically reducing emissions, thereby accentuating the growth in aircraft emissions. For instance, from a local/regional perspective the 1999 EPA study, *Evaluation of Air Pollutant Emissions from Subsonic Commercial*

Jet Aircraft, reported that from 1990 to 2010 increases in commercial aircraft NO_x emissions for the ten cities studied (19 airport facilities with significant commercial jet aircraft activity were identified within these selected cities) are expected to range from 50 to 110 percent.¹⁶ As an average for the ten cities, commercial aircraft's contribution to regional mobile source NO_x was anticipated to increase from about 2 percent in 1990 to about 5 percent in 2010. In addition, the study showed that in 2010 commercial aircraft are projected to contribute as much as 10 percent of total regional mobile source NO_x emissions in at least two of the cities studied.¹⁷

(The above projections were made prior to the tragic events of September 11, 2001, and the subsequent economic downturn. A January 2003 report by the Department of Transportation indicated that the combination of the September 11, 2001 terrorist attacks and a cut-back in business travel had a significant and perhaps long-lasting effect on air traffic demand.¹⁸ However, the FAA expects the demand for air travel to recover, and then continue a long-term trend of annual growth in the United States.¹⁹ Recently, FAA reported that flights of commercial air carriers will increase by 18 percent from 2002 to 2010 and 45 percent from 2002 to 2020.²⁰ For a

¹⁶ This study (EPA 420-R-99-013, April 1999) is available at <http://www.epa.gov/otaq/aviation.htm>. It can also be found in Docket No. OAR-2002-0030.

¹⁷ Based on the one-hour ozone standard, nine of the ten metropolitan areas are currently not in attainment of NAAQS for ozone; the tenth city has attained the ozone standard and is considered an ozone "maintenance" area. See section III.A.1. of this proposal for further discussion on the ozone NAAQS. Also, for more detailed information on the 8-hour ozone standard, see the following EPA Web sites:

<http://www.epa.gov/airlinks/ozpminfo.html>, <http://www.epa.gov/airlinks/airlinks4.html> or <http://www.epa.gov/ttn/naaqs/ozone/o3imp8hr>. EPA has not yet designated areas for the 8-hour standard.

¹⁸ U.S. Department of Transportation, Office of Inspector General, "Airline Industry Metrics," CC-2203-007, January 7, 2003. A copy of this document can be found in Docket No. OAR-2002-0030.

¹⁹ U.S. General Accounting Office, "Aviation and the Environment: Strategic Framework Needed to Address Challenges Posed by Aircraft Emissions," GAO-03-252, February 2003. This document is available at www.gao.gov/cgi-bin/getrpt?GAO-03-252, and it can also be found in the Docket No. OAR-2002-0030.

²⁰ The flight forecast data is based on FAA's Terminal Area Forecast System (TAFS). TAFS is the official forecast of aviation activity at FAA facilities. This includes FAA-towered airports, federally-contracted towered airports, nonfederal towered airports, and many non-towered airports. For detailed information on TAFS and the air carrier activity forecasts see the following FAA Web site: <http://www.apo.data.faa.gov/faatafall.HTM>. As of May 1, 2003, the aviation forecasts contained in TAFS for Fiscal Years 2002-2020 included the impact of the terrorists' attacks of September 11, 2001 and the recent economic downturn. However,

¹³ CAA section 233 entitled "State Standards and Controls" states that "No State or political subdivision thereof may adopt or attempt to enforce any standard respecting emissions of any air pollutant from any aircraft or engine thereof unless such standard is identical to a standard applicable to such aircraft under this part."

¹⁴ U.S. EPA, "Average Annual Emissions, All Criteria Pollutants Years Including 1980, 1985, 1989-2001," February 2003. This document is available at <http://www.epa.gov/ttnchie1/trends/>. A copy of this document can also be found in Docket No. OAR-2002-30. Documentation for these estimates can be accessed at <http://www.epa.gov/ttn/chief/net/index.html#1999>: U.S. EPA, "Documentation for Aircraft, Commercial Marine Vessel, Locomotive, and Other Nonroad Components of the National Emissions Inventory, Volume I—Methodology," November 11, 2002. A copy of this document can also be found in Docket No. OAR-2002-30.

¹⁵ Commercial aircraft include those aircraft used for scheduled service transporting passengers, freight, or both. Air taxis also fly scheduled service carrying passengers, freight or both, but usually are smaller aircraft and operate on a more limited basis than commercial carriers. General aviation includes most other aircraft used for recreational flying and personal transportation. Aircraft that support business travel, usually on an unscheduled basis, are included in the category of general aviation. Military aircraft cover a wide range of sizes, uses, and operating missions. While they are often similar to civil aircraft, they are handled separately because they typically operate exclusively out of military bases and frequently have distinctive flight profiles.

comparison of an earlier (pre-9/11) FAA activity forecast to a recent (post-9/11) forecast, see the below table. We request comment on the effect that September

11, 2001, and the subsequent economic downturn have had on the projected growth of commercial aircraft emissions. Your comments will be most

useful if you include appropriate and detailed supporting data and analysis.)

TABLE III-1.—FAA TERMINAL AREA FORECAST SUMMARY REPORT OF NATIONWIDE AIR CARRIER OPERATIONS²¹

| Year | Air carrier operations 12/14/00 forecast (pre-9/11) | Percent change 12/14/00 forecast between years listed | Air carrier operations 5/1/03 forecast (post-9/11) | Percent change 5/1/03 forecast between years listed |
|-------------------------|---|---|--|---|
| 1999 | 15,127,419 | | 14,776,055 | |
| 2000 | 15,476,135 | 2.3 | 15,265,682 | 3.3 |
| 2001 | 15,819,505 | 2.2 | 14,807,303 | -3.0 |
| 2002 ^a | 16,210,777 | 2.5 | 13,255,837 | -10 |
| 2005 | 17,455,705 | 7.6 | 13,918,058 | 5.0 |
| 2010 | 19,664,128 | 14 | 15,608,349 | 13 |
| 2015 | 22,004,067 | 12 | 17,372,200 | 11 |
| 2020 | N/A ^b | — | 19,249,778 | 11 |

^a The change in operations from 2000 to 2002 was +4.7% for the 12/14/00 forecast, and it was -13% for the 5/1/03 forecast.

^b N/A = Not available.

Air pollutants resulting from airport operations are emitted from several types of sources: aircraft main engines and auxiliary power units (APUs); ground support equipment (GSE), which include vehicles such as aircraft tugs, baggage tugs, fuel trucks, maintenance vehicles, and other miscellaneous vehicles used to support aircraft operations; ground access vehicles (GAV), which include vehicles from off-site used by passengers, employees, freight operators, and other persons utilizing an airport. EPA's previous estimates show aircraft engines comprise approximately 45 percent of total air pollutant emissions from airport operations; GAV account for another 45 percent, and APUs and GSE combined make up the remaining 10

percent.²² Since EPA has established stringent emission standards for GAVs and other motor vehicles that will be manufactured and introduced into commerce in future years, overall emissions from these vehicles will continue to decline for many years.

The emissions from aircraft engines that are being directly controlled by the standards proposed in this rulemaking are NO_x. As discussed later in this section, NO_x emissions at low altitude also react in the atmosphere to form secondary particulate matter (PM_{2.5}),²³ which is namely ammonium nitrate, and thus, secondary PM would be effected as a consequence of the proposed standards. Adopting standards equivalent to the latest ICAO NO_x emission standards and the related

ICAO test procedures would help in achieving and/or maintaining compliance with the NAAQS for ozone (O₃) and PM.

There are about 111 million people living in counties with monitored concentrations exceeding the 8-hour ozone NAAQS, and over 65 million people living in counties with monitored PM_{2.5} levels exceeding the PM_{2.5} NAAQS. Figure III.-1 illustrates the widespread nature of these problems. Shown in this figure are counties exceeding either or both of the two NAAQS plus mandatory Federal Class I areas, which have particular needs for reductions in atmospheric haze. A discussion of the adverse effects on public health and welfare associated with these pollutants is provided below.

these projections did not fully reflect the ongoing structural changes occurring within the aviation industry. A copy of the May 1, 2003 forecast summary report for air carrier activity can be found in Docket No. OAR-2002-0030.

²¹ A copy of FAA's 12/14/00 forecast summary report (from TAFS) for air carrier activity can be found in Docket No. OAR-2002-0030.

²² The California FIP, signed by the Administrator 2/14/95, is located in EPA Air Docket A-94-09,

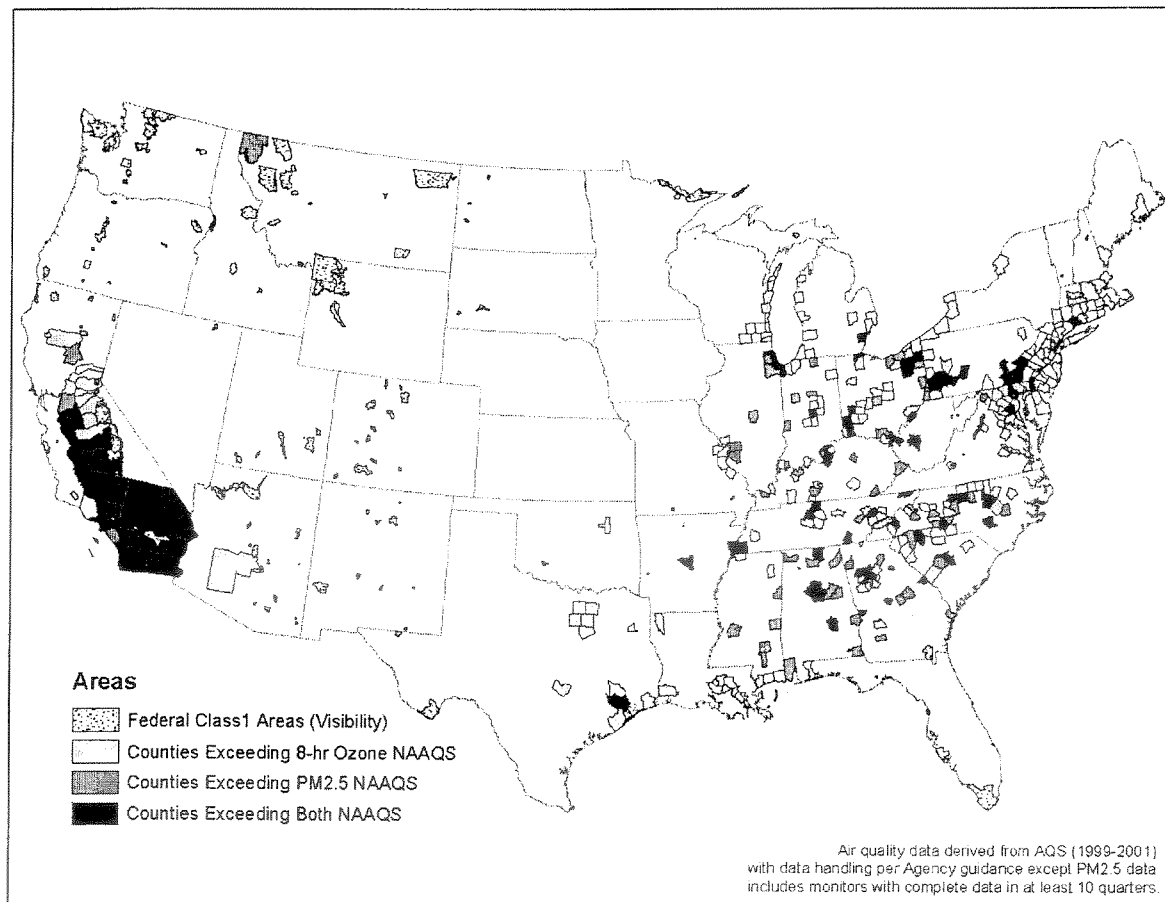
item number V-A-1. The FIP was vacated by an act of Congress before it became effective.

In addition, the 1997 EPA Draft Final Report entitled, "Analysis of Techniques to Reduce Air Emission at Airports" (prepared by Energy and Environmental Analysis, Inc.), it was estimated that for the four airports studied (which are large air traffic hubs) on average aircraft compromise approximately 35 percent of NO_x emissions from airport operations; GAV account for another 35

percent, and APUs and GSE contribute about 15 percent each for the remaining 30 percent. This document can be found in Docket No. OAR-2002-0030.

²³ As described later in section III.A.2., fine particles refer to those particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers (also known as PM_{2.5}).

FIGURE III-1 -- AIR QUALITY PROBLEMS ARE WIDESPREAD



A. Public Health Impacts

1. Ozone

a. *What are the health effects of ozone pollution?* Ground-level ozone pollution (sometimes called "smog") is formed by the reaction of nitrogen oxides (NO_x) and volatile organic compounds (VOC) in the atmosphere in the presence of heat and sunlight.²⁴ Ozone can irritate the respiratory system, causing coughing, throat irritation, and/or uncomfortable sensation in the chest.^{25,26} Ozone can reduce lung function and make it more difficult to breathe deeply, and breathing may become more rapid and shallow than normal, thereby limiting a person's normal activity. Ozone also can aggravate asthma, leading to more

asthma attacks that require a doctor's attention and/or the use of additional medication. In addition, ozone can inflame and damage the lining of the lungs, which may lead to permanent changes in lung tissue, irreversible reductions in lung function, and a lower quality of life if the inflammation occurs repeatedly over a long time period (months, years, a lifetime). People who are of particular concern with respect to ozone exposures include children and adults who are active outdoors. Those people particularly susceptible to ozone effects are people with respiratory disease, such as asthma, and people with unusual sensitivity to ozone, and children. Beyond its human health effects, ozone has been shown to injure plants, which has the effect of reducing

crop yields and reducing productivity in forest ecosystems.^{27,28}

The 8-hour ozone standard, established by EPA in 1997, is based on well-documented science demonstrating that more people are experiencing adverse health effects at lower levels of exertion, over longer periods, and at lower ozone concentrations than addressed by the one-hour ozone standard. (See, e.g., 62 FR 38861-38862, July 18, 1997). The 8-hour standard addresses ozone exposures of concern for the general population and populations most at risk, including

²⁴ U.S. EPA, "Nitrogen Oxides: Impacts on Public Health and the Environment," EPA 452/R-97-002, August 1997. A copy of this document is available in Docket No. OAR 2002-0030.

²⁵ U.S. EPA (1996). Air Quality Criteria for Ozone and Related Photochemical Oxidants, EPA/600/P-93/004aF. Docket No. A-99-06. Document Nos. II-A-15 to 17.

²⁶ U.S. EPA. (1996). Review of National Ambient Air Quality Standards for Ozone, Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-96-007. Docket No. A-99-06. Document No. II-A-22.

²⁷ U.S. EPA (1996). Air Quality Criteria for Ozone and Related Photochemical Oxidants, EPA/600/P-93/004aF. Docket No. A-99-06. Document Nos. II-A-15 to 17.

²⁸ U.S. EPA. (1996). Review of National Ambient Air Quality Standards for Ozone, Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA-452/R-96-007. Docket No. A-99-06. Document No. II-A-22.

children active outdoors, outdoor workers, and individuals with pre-existing respiratory disease, such as asthma.

There has been new research that suggests additional serious health effects beyond those that had been known when the 8-hour ozone health standard was set. Since 1997, over 1,700 new health and welfare studies relating to ozone have been published in peer-reviewed journals.²⁹ Many of these studies have investigated the impact of ozone exposure on such health effects as changes in lung structure and biochemistry, inflammation of the lungs, exacerbation and causation of asthma, respiratory illness-related school absence, hospital and emergency room visits for asthma and other respiratory causes, and premature mortality. EPA is currently in the process of evaluating these and other studies as part of the ongoing review of the air quality criteria and NAAQS for ozone. A revised Air Quality Criteria Document for Ozone and Other Photochemical Oxidants will be prepared in consultation with EPA's Clean Air Science Advisory Committee (CASAC). Key new health information falls into four general areas: development of new-onset asthma, hospital admissions for young children, school absence rate, and premature mortality.

Aggravation of existing asthma resulting from short-term ambient ozone exposure was reported prior to the 1997 decision and has been observed in studies published subsequently.^{30,31} In particular, a relationship between long-term ambient ozone concentrations and the incidence of new-onset asthma in adult males (but not in females) was reported by McDonnell *et al.* (1999).³² Subsequently, an additional study suggests that incidence of new diagnoses of asthma in children is associated with heavy exercise in

communities with high concentrations (*i.e.*, mean 8-hour concentration of 59.6 ppb) of ozone.³³ This relationship was documented in children who played 3 or more sports and thus had higher exposures and was not documented in those children who played one or two sports. The larger effect of high activity sports than low activity sports and an independent effect of time spent outdoors also in the higher ozone communities strengthened the inference that exposure to ozone may modify the effect of sports on the development of asthma in some children.

Previous studies have shown relationships between ozone and hospital admissions in the general population. A study in Toronto reported a significant relationship between 1-hour maximum ozone concentrations and respiratory hospital admissions in children under the age of two.³⁴ Given the relative vulnerability of children in this age category, we are particularly concerned about the findings.

Increased respiratory diseases that are serious enough to cause school absences have been associated with 1-hour daily maximum and 8-hour average ozone concentrations in studies conducted in Nevada³⁵ in kindergarten to 6th grade and in Southern California in grades 4 through 6.³⁶ These studies suggest that higher ambient ozone levels may result in increased school absenteeism.

The air pollutant most clearly associated with premature mortality is PM, with dozens of studies reporting such an association. However, repeated ozone exposure is a possible contributing factor for premature mortality, causing an inflammatory response in the lungs which may predispose elderly and other sensitive individuals to become more susceptible to other stressors, such as PM.^{37,38,39}

²⁹ McConnell, R.; Berhane, K.; Gilliland, F.; London, S. J.; Islam, T.; Gauderman, W. J.; Avol, E.; Margolis, H. G.; Peters, J. M. (2002) Asthma in exercising children exposed to ozone: a cohort study. *Lancet* 359: 386–391.

³⁰ Burnett, R. T.; Smith-Doiron, M.; Stieb, D.; Raizenne, M. E.; Brook, J. R.; Dales, R. E.; Leech, J. A.; Cakmak, S.; Krewski, D. (2001) Association between ozone and hospitalization for acute respiratory diseases in children less than 2 years of age. *Am. J. Epidemiol.* 153: 444–452.

³¹ Chen, L.; Jennison, B. L.; Yang, W.; Omaye, S. T. (2000) Elementary school absenteeism and air pollution. *Inhalation Toxicol.* 12:997–1016.

³² Gilliland, F.D.; Berhane, E.B.; Rappaport, D.C.; Thomas, E.; Avol, W.J.; Gauderman, S.J.; London, H.G.; Margolis, R.; McConnell, K.T.; Islam, J.M.; Peters (2001) The effects of ambient air pollution on school absenteeism due to respiratory illnesses. *Epidemiology* 12:43–54.

³³ Samet JM, Zeger SL, Dominici F, Curriero F, Coursac I, Dockery DW, Schwartz J, Zanobetti A. 2000. The National Morbidity, Mortality and Air Pollution Study: Part II: Morbidity, Mortality and Air Pollution in the United States. Research Report

Although the findings have been mixed, the findings of three recent analyses suggest that ozone exposure is associated with increased mortality. Although the National Morbidity, Mortality, and Air Pollution Study (NMMAPS) did not report an effect of ozone on total mortality across the full year, the investigators who conducted the NMMAPS study did observe an effect after limiting the analysis to summer when ozone levels are highest.^{40,41} Similarly, other studies have shown associations between ozone and mortality.^{42,43} Specifically, Touloumi *et al.* (1997) found that 1-hour maximum ozone levels were associated with daily numbers of deaths in 4 cities (London, Athens, Barcelona, and Paris), and a quantitatively similar effect was found in a group of four additional cities (Amsterdam, Basel, Geneva, and Zurich).

In all, the new studies that have become available since the 8-hour ozone standard was adopted in 1997 continue to demonstrate the harmful effects of ozone on public health, and the need to attain and maintain the NAAQS.

b. *Current and projected 8-hour ozone levels.* The current primary and secondary ozone NAAQS is 0.12 ppm daily maximum 1-hour concentration, not to be exceeded more than once per year on average. EPA is replacing the previous 1-hour ozone standard with a new 8-hour standard. The new standard

No. 94, Part II. Health Effects Institute, Cambridge, MA, June 2000. (Docket Number A-2000-01, Document Nos. IV-A-208 and 209).

³⁸ Devlin, R. B.; Polinsbee, L. J.; Biscardi, F.; Hatch, G.; Becker, S.; Madden, M. C.; Robbins, M.; Koren, H. S. (1997) Inflammation and cell damage induced by repeated exposure of humans to ozone. *Inhalation Toxicol.* 9: 211–235.

³⁹ Koren HS, Devlin RB, Graham DE, Mann R, McGee MP, Horstman DH, Kozumbo WJ, Becker S, House DE, McDonnell SF, Bromberg, PA. 1989. Ozone-induced inflammation in the lower airways of human subjects. *Am. Rev. Respir. Dis.* 139:407–415.

⁴⁰ Samet JM, Zeger SL, Dominici F, Curriero F, Coursac I, Dockery DW, Schwartz J, Zanobetti A. 2000. The National Morbidity, Mortality and Air Pollution Study: Part II: Morbidity, Mortality and Air Pollution in the United States. Research Report No. 94, Part II. Health Effects Institute, Cambridge MA, June 2000. (Docket Number A-2000-01, Documents No. IV-A-208 and 209)

⁴¹ Samet JM, Zeger SL, Dominici F, Curriero F, Coursac I, Zeger, S. Fine Particulate Air Pollution and Mortality in 20 U.S. Cities, 1987–1994. *The New England Journal of Medicine*. Vol. 343, No. 24, December 14, 2000. P. 1742–1749.

⁴² Thurston, G. D.; Ito, K. (2001) Epidemiological studies of acute ozone exposures and mortality. *J. Exposure Anal. Environ. Epidemiol.* 11: 286–294.

⁴³ Touloumi, G.; Katsouyanni, K.; Zmirou, D.; Schwartz, J.; Spix, C.; Ponce de Leon, A.; Tobias, A.; Quenell, P.; Rabeczenko, D.; Bacharova, L.; Bisanti, L.; Vonk, J. M.; Ponka, A. (1997) Short-term effects of ambient oxidant exposure on mortality: a combined analysis within the APHEA project. *Am. J. Epidemiol.* 146: 177–185.

²⁹ New Ozone Health and Environmental Effects References, Published Since Completion of the Previous Ozone AQCD, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711 (7/2002). A copy of this document is available in Docket No. OAR 2002-0030.

³⁰ Thurston, G.D., M.L. Lippman, M.B. Scott, and J.M. Fine. 1997. Summertime Haze Air Pollution and Children with Asthma. *American Journal of Respiratory Critical Care Medicine*, 155: 654–660.

³¹ Ostro, B., M. Lipsett, J. Mann, H. Braxton-Owens, and M. White (2001) Air pollution and exacerbation of asthma in African-American children in Los Angeles. *Epidemiology* 12(2): 200–208.

³² McDonnell, W.F., D.E. Abbey, N. Nishino and M.D. Lebowitz. 1999. "Long-term ambient ozone concentration and the incidence of asthma in nonsmoking adults: the ahsnog study." *Environmental Research*. 80(2 Pt 1): 110–121.

is set at a concentration of 0.08 parts per million (ppm), and the measurement period is 8 hours. Areas are allowed to disregard their three worst measurements every year and average performance over three years to determine if they meet the standard. That is, the standard is set by the 4th highest maximum 8-hour concentration.

As shown earlier (Figure III–1) unhealthy ozone concentrations exceeding the level of the 8-hour standard (*i.e.*, not requisite to protect the public health with an adequate margin of safety) occur over wide geographic areas, including most of the nation's major population centers. These monitored areas include much of the eastern half of the U.S. and large areas of California.

Based upon data from 1999–2001, there are 291 counties where 111 million people live that are measuring values that violate the 8-hour ozone NAAQS.⁴⁴ An additional 37 million people live in 155 counties that have air quality measurements within 10 percent of the level of the standard.⁴⁵ These areas, though currently not violating the standard, would also benefit from the additional emission reductions from this proposed rule.

From air quality modeling performed for the recent Nonroad Diesel Engines and Fuel Control proposed rule,⁴⁶ we anticipate that without emission reductions beyond those already required under promulgated regulation and approved State Implementation Plans (SIPs), ozone nonattainment will likely persist into the future. With reductions from programs already in place, the number of counties violating the ozone 8-hour standard is expected to decrease in 2020 to 30 counties where 43 million people are projected to live. Thereafter, exposure to unhealthy levels of ozone is expected to begin to increase again. In 2030 the number of counties violating the ozone 8-hour NAAQS is projected to increase to 32 counties where 47 million people are projected to live. In addition, in 2030, 82 counties where 44 million people are projected to

live will be within 10 percent of violating the ozone 8-hour NAAQS.

EPA is still developing the implementation process for bringing the nation's air into attainment with the ozone 8-hour NAAQS. On June 2, 2003 (68 FR 32802), EPA issued a proposal for the implementation process to bring the nation's air into attainment with the 8-hour ozone NAAQS.⁴⁷ The proposal seeks comment on options for planning and control requirements, along with options for making the transition from the 1-hour ozone standard to the 8-hour ozone standard. The proposal does not designate nonattainment area for the 8-hour ozone NAAQS; EPA's current plans calls for designating 8-hour ozone nonattainment areas in April 2004, under a separate process. EPA has proposed that States submit SIPs that address how areas will attain the 8-hour ozone standard within 3 years after nonattainment designation for moderate and above areas classified under subpart 2 and for some areas classified under subpart 1. EPA is also proposing that marginal areas and some areas designated under subpart 1 (*i.e.*, those with early attainment dates) will not be required to submit attainment demonstrations for the 8-hour ozone standard. We therefore anticipate that States will submit their attainment demonstration SIPs by April 2007.

The Act contains two sets of requirements—subpart 1 and subpart 2—that establish requirements for State plans implementing the national ozone air quality standards in nonattainment areas. (Both are found in title I, part D.) Subpart 1 contains general requirements for SIPs for nonattainment areas for any pollutant—including ozone—governed by a NAAQS. Subpart 2 provides more specific requirements for ozone nonattainment SIPs. Under subpart 1 of part D, title I of the Act demonstrate that the nonattainment areas will attain the ozone 8-hour standard as expeditiously as practicable but no later than five years from the date that the area was designated nonattainment. However, based on the severity of the air quality problem and the availability and feasibility of control measures, the Administrator may extend the attainment date “for a period of no greater than 10 years from the date of designation as nonattainment.” Based on these provisions, we expect that most or all areas covered under subpart 1 will attain the ozone standard in the 2007 to 2014 time frame. For areas covered

under subpart 2, the maximum attainment dates provided under the Act range from 3 to 20 years after designation, depending on an area's classification. Thus, we anticipate that areas covered by subpart 2 will attain in the 2007 to 2024 time period.

Since the emission reductions expected from this proposed rule would occur during the time period when areas will need to attain the standard under either option, projected reductions in aircraft engine emissions would assist States in their effort to meet the new NAAQS. Such reductions would help them attain and maintain the 8-hour NAAQS.

2. Particulate Matter

NO_x emitted at low altitude is also a precursor in the formation of some nitrate particulate matter (PM) in the atmosphere (mostly ammonium nitrate).^{48,49} Essentially all nitrate PM is of such a diameter that it is respirable in humans. As discussed earlier, aircraft account for over 1 percent of the total U.S. mobile source NO_x emissions, and aircraft's contribution to nationwide secondary PM from U.S. mobile source NO_x is expected to be relatively similar.⁵⁰

Particulate matter represents a broad class of chemically and physically diverse substances. It can be principally characterized as discrete particles that exist in the condensed (liquid or solid) phase spanning several orders of magnitude in size. PM₁₀ refers to particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers. Fine particles refer to those particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers (also known as PM_{2.5}), and coarse fraction particles are those particles with an aerodynamic diameter greater than 2.5 microns, but less than or equal to a nominal 10 micrometers. Ultrafine PM refers to particles with diameters of less than 100 nanometers (0.1 micrometers). The health and environmental effects of PM are associated with fine PM fraction and, in some cases, to the size of the particles.

⁴⁸ Secondary PM is formed when NO_x reacts with ammonia in the atmosphere to yield ammonium nitrate particulate.

⁴⁹ U.S. EPA, “Nitrogen Oxides: Impacts on Public Health and the Environment,” EPA 452/R-97-002, August 1997. A copy of this document is available in Docket No. OAR 2002-0030.

⁵⁰ “Benefits of Mobile Source NO_x Related Particulate Matter Reductions,” Systems Applications International, EPA Contract No. 68-C5-0010, WAN 1-8, October 1996. A copy of this document is available in Docket No. OAR-2002-0030. This report concluded that, as a national average, each 100 tons of NO_x emissions will result in about 4 tons of secondary PM (conversion rate was about 0.04). This conversion rate varies from region to region, and is greatest in the West.

⁴⁴ Additional counties may have levels above the NAAQS but do not currently have monitors.

⁴⁵ Memorandum to Docket A-2001-11 from Fred Dimmick, Group Leader, Air Trends Group, “Summary of Currently Available Air Quality Data and Ambient Concentrations for Ozone and Particulate Matter,” December 3, 2002. A copy of this document is available in Docket No. OAR 2002-0030.

⁴⁶ See the Regulatory Impact Analysis: “Draft Regulatory Impact Analysis: Control of Emissions from Nonroad Diesel Engines,” EPA420-R-03-008, April 2003. This document is available at <http://www.epa.gov/nonroad/>. A copy of this document can also be found in Docket No. A-2001-28.

⁴⁷ A copy of this proposed rule entitled, “Proposed Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard,” is available at: <http://www.epa.gov/ttn/naaqs/ozone/o3imp8hr>.

Specifically, larger particles ($>10\ \mu\text{m}$) tend to be removed by the respiratory clearance mechanisms whereas smaller particles are deposited deeper in the lungs. Also, particles scatter light obstructing visibility.

The emission sources, formation processes, chemical composition, atmospheric residence times, transport distances and other parameters of fine and coarse particles are distinct. Fine particles are directly emitted from combustion sources and are formed secondarily from gaseous precursors such as oxides of nitrogen (NO_x). Fine particles are generally composed of sulfate, nitrate, chloride, ammonium compounds, organic carbon, elemental carbon, and metals. Aircraft engines emit NO_x which react in the atmosphere to form secondary $\text{PM}_{2.5}$ (namely ammonium nitrate). Combustion of coal, oil, diesel, gasoline, and wood, as well as high temperature process sources such as smelters and steel mills, produce emissions that contribute to fine particle formation. In contrast, coarse particles are typically mechanically generated by crushing or grinding. They include resuspended dusts and crustal material from paved roads, unpaved roads, construction, farming, and mining activities. These coarse particles can be either natural in source such as road dust or anthropogenic. Fine particles can remain in the atmosphere for days to weeks and travel through the atmosphere hundreds to thousands of kilometers, while coarse particles deposit to the earth within minutes to hours and within tens of kilometers from the emission source.

The relative contribution of various chemical components to $\text{PM}_{2.5}$ varies by region of the country. Data on $\text{PM}_{2.5}$ composition are available from the EPA Speciation Trends Network in 2001 and the Interagency Monitoring of PROtected Visual Environments (IMPROVE) network in 1999 covering both urban and rural areas in numerous regions of the U.S. These data show that nitrates formed from NO_x also play a major role in the western U.S., especially in the California area where it is responsible for about a quarter of the ambient $\text{PM}_{2.5}$ concentrations.

a. Health Effects of $\text{PM}_{2.5}$

Scientific studies show ambient PM is associated with a series of adverse health effects. These health effects are discussed in detail in the EPA Criteria Document for PM as well as the draft

updates of this document released in the past year.^{51,52}

As described in these documents, health effects associated with short-term variation in ambient particulate matter (PM) have been indicated by epidemiologic studies showing associations between exposure and increased hospital admissions for ischemic heart disease, heart failure, respiratory disease, including chronic obstructive pulmonary disease (COPD) and pneumonia. Short-term elevations in ambient PM have also been associated with increased cough, lower respiratory symptoms, and decrements in lung function. Short-term variations in ambient PM have also been associated with increases in total and cardiorespiratory daily mortality. Studies examining populations exposed to different levels of air pollution over a number of years, including the Harvard Six Cities Study and the American Cancer Society Study suggest an association between exposure to ambient $\text{PM}_{2.5}$ and premature mortality, including deaths attributed to lung cancer.^{53,54} Two studies further analyzing the Harvard Six Cities Study's air quality data have also established a specific influence of mobile source-related $\text{PM}_{2.5}$ on daily mortality⁵⁵ and a concentration-response function for mobile source-associated $\text{PM}_{2.5}$ and daily mortality.⁵⁶

b. Current and Projected Levels

There are NAAQS for both PM_{10} and $\text{PM}_{2.5}$. Violations of the annual $\text{PM}_{2.5}$ standard are much more widespread than are violations of the PM_{10} standards. Figure III-1 at the beginning of this air quality section highlighted

monitor locations measuring concentrations above the level of the NAAQS. As can be seen from that figure, high ambient levels are widespread throughout the country. Today's proposed aircraft NO_x standards should contribute to attainment and maintenance of the existing PM NAAQS since NO_x contributes to the secondary formation of $\text{PM}_{2.5}$.

The NAAQS for $\text{PM}_{2.5}$ were established by EPA in 1997 (62 FR 38651, July 18, 1997). The short term (24-hour) standard is set at a level of $65\ \mu\text{g}/\text{m}^3$ based on the 98th percentile concentration averaged over three years. (This air quality statistic compared to the standard is referred to as the "design value.") The long-term standard specifies an expected annual arithmetic mean not to exceed $15\ \mu\text{g}/\text{m}^3$ averaged over three years.

Current $\text{PM}_{2.5}$ monitored values for 1999–2001, which cover counties having about 75 percent of the country's population, indicate that at least 65 million people in 129 counties live in areas where annual design values of ambient fine PM violate the $\text{PM}_{2.5}$ NAAQS. There are an additional 9 million people in 20 counties where levels above the NAAQS are being measured, but there are insufficient data at this time to calculate a design value in accordance with the standard, and thus determine whether these areas are violating the $\text{PM}_{2.5}$ NAAQS. In total, this represents 37 percent of the counties and 64 percent of the population in the areas with monitors with levels above the NAAQS.⁵⁷ Furthermore, an additional 14 million people live in 41 counties that have air quality measurements within 10 percent of the level of the standard. These areas, although not currently violating the standard, would also benefit from the additional reductions from this proposed rule in order to help ensure long term maintenance.

The air quality modeling performed for the recent Nonroad Diesel Engines and Fuel Control proposed rule also indicates that similar conditions are likely to continue to exist in the future

⁵¹ U.S. EPA (1996.) Air Quality Criteria for Particulate Matter—Volumes I, II, and III, EPA, Office of Research and Development. Report No. EPA/600/P-95/001a-cF. This material is available electronically at <http://www.epa.gov/ttn/oarpg/ticd.html>. Available in Docket A-99-06, Document Nos. IV-A-30, IV-A-31, and IV-A-32.

⁵² U.S. EPA (2002). Air Quality Criteria for Particulate Matter—Volumes I and II (Third External Review Draft) This material is available electronically at <http://cfpub.epa.gov/ncea/cfm/partmatt.cfm>. Available in Docket A-2001-28, Document Nos. II-A-98 and II-A-71.

⁵³ Dockery, DW; Pope, CA, III; Xu, X; *et al.* (1993) An association between air pollution and mortality in six U.S. cities. *N Engl J Med* 329:1753–1759.

⁵⁴ Pope, CA, III; Thun, MJ; Namboordiri, MM; *et al.* (1995) Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. *Am J Respir Crit Care Med* 151:669–674.

⁵⁵ Laden F; Neas LM; Dockery DW; *et al.* (2000) Association of fine particulate matter from different sources with daily mortality in six U.S. cities. *Environ Health Perspect* 108(10):941–947.

⁵⁶ Schwartz J; Laden F; Zanobetti A. (2002) The concentration-response relation between $\text{PM}_{2.5}$ and daily deaths. *Environ Health Perspect* 110(10):1025–1029.

⁵⁷ Memorandum to Docket A-2001-11 from Fred Dimmick, Group Leader, Air Trends Group, "Summary of Currently Available Air Quality Data and Ambient Concentrations for Ozone and Particulate Matter," December 3, 2002. A copy of this document is available in Docket No. OAR 2002-0030.

in the absence of additional controls.⁵⁸ For example, in 2020 based on emission controls currently adopted, we project that 66 million people will live in 79 counties with average PM_{2.5} levels above 15 µg/m³. In 2030, the number of people projected to live in areas exceeding the PM_{2.5} standard is expected to increase to 85 million in 107 counties. An additional 24 million people are projected to live in counties within 10 percent of the standard in 2020, which will increase to 64 million people in 2030.

While the final implementation process for bringing the nation's air into attainment with the PM_{2.5} NAAQS is still being completed in a separate rulemaking action, the basic framework is well defined by the statute. EPA's current plans call for designating PM_{2.5} nonattainment areas in late 2004. Following designation, section 172(b) of the Clean Air Act allows states up to three years to submit a revision to their state implementation plan (SIP) that provides for the attainment of the PM_{2.5} standard. Based on this provision, states could submit these SIPs as late as the end of 2007. Section 172(a)(2) of the Clean Air Act requires that these SIP revisions demonstrate that the nonattainment areas will attain the PM_{2.5} standard as expeditiously as practicable but no later than five years from the date that the area was designated nonattainment. However, based on the severity of the air quality problem and the availability and feasibility of control measures, the Administrator may extend the attainment date "for a period of no greater than 10 years from the date of designation as nonattainment." Therefore, based on this information, we expect that most or all areas will need to attain the PM_{2.5} NAAQS in the 2009 to 2014 time frame, and then be required to maintain the NAAQS thereafter.

B. Other Environmental Effects

The following section presents information on four categories of public welfare and environmental impacts related to NO_x and fine PM emissions: acid deposition, eutrophication of water bodies, plant damage from ozone, and visibility impairment.

1. Acid Deposition

Acid deposition, or acid rain as it is commonly known, occurs when NO_x

and SO₂ react in the atmosphere with water, oxygen, and oxidants to form various acidic compounds that later fall to earth in the form of precipitation or dry deposition of acidic particles.⁵⁹ It contributes to damage of trees at high elevations and in extreme cases may cause lakes and streams to become so acidic that they cannot support aquatic life. In addition, acid deposition accelerates the decay of building materials and paints, including irreplaceable buildings, statues, and sculptures that are part of our nation's cultural heritage. To reduce damage to automotive paint caused by acid rain and acidic dry deposition, some manufacturers use acid-resistant paints, at an average cost of \$5 per vehicle—a total of \$80–85 million per year when applied to all new cars and trucks sold in the U.S.

Acid deposition primarily affects bodies of water that rest atop soil with a limited ability to neutralize acidic compounds. The National Surface Water Survey (NSWS) investigated the effects of acidic deposition in over 1,000 lakes larger than 10 acres and in thousands of miles of streams. It found that acid deposition was the primary cause of acidity in 75 percent of the acidic lakes and about 50 percent of the acidic streams, and that the areas most sensitive to acid rain were the Adirondacks, the mid-Appalachian highlands, the upper Midwest and the high elevation West. The NSWS found that approximately 580 streams in the Mid-Atlantic Coastal Plain are acidic primarily due to acidic deposition. Hundreds of the lakes in the Adirondacks surveyed in the NSWS have acidity levels incompatible with the survival of sensitive fish species. Many of the over 1,350 acidic streams in the Mid-Atlantic Highlands (mid-Appalachia) region have already experienced trout losses due to increased stream acidity. Emissions from U.S. sources contribute to acidic deposition in eastern Canada, where the Canadian government has estimated that 14,000 lakes are acidic. Acid deposition also has been implicated in contributing to degradation of high-elevation spruce forests that populate the ridges of the Appalachian Mountains from Maine to Georgia. This area includes national parks such as the Shenandoah and Great Smoky Mountain National Parks.

⁵⁹ Much of the information in this subsection was excerpted from the EPA document, *Human Health Benefits from Sulfate Reduction*, written under Title IV of the 1990 Clean Air Act Amendments, U.S. EPA, Office of Air and Radiation, Acid Rain Division, Washington, DC 20460, November 1995. A copy of this document is available in Docket No. OAR 2002-0030.

A study of emissions trends and acidity of water bodies in the Eastern U.S. by the General Accounting Office (GAO) found that from 1992 to 1999 sulfates declined in 92 percent of a representative sample of lakes, and nitrate levels increased in 48 percent of the lakes sampled.⁶⁰ The decrease in sulfates is consistent with emissions trends, but the increase in nitrates is inconsistent with the stable levels of nitrogen emissions and deposition. The study suggests that the vegetation and land surrounding these lakes have lost some of their previous capacity to use nitrogen, thus allowing more of the nitrogen to flow into the lakes and increase their acidity. Recovery of acidified lakes is expected to take a number of years, even where soil and vegetation have not been "nitrogen saturated," as EPA called the phenomenon in a 1995 study.⁶¹ This situation places a premium on reductions of NO_x (and SO_x) from all sources, including aircraft engines, in order to reduce the extent and severity of nitrogen saturation and acidification of lakes in the Adirondacks and throughout the U.S.

The NO_x reductions from today's action would help reduce acid rain and acid deposition, thereby helping to reduce acidity levels in lakes and streams throughout the country and help accelerate the recovery of acidified lakes and streams and the revival of ecosystems adversely affected by acid deposition. Reduced acid deposition levels will also help reduce stress on forests, thereby accelerating reforestation efforts and improving timber production. Deterioration of our historic buildings and monuments, and of buildings, vehicles, and other structures exposed to acid rain and dry acid deposition also will be reduced, and the costs borne to prevent acid-related damage may also decline. While the reduction in nitrogen acid deposition would be roughly proportional to the reduction in NO_x emissions the precise impact of today's action would differ across different areas.

2. Eutrophication and Nitrification

Eutrophication is the accelerated production of organic matter, particularly algae, in a water body. This

⁵⁸ See the Regulatory Impact Analysis: "Draft Regulatory Impact Analysis: Control of Emissions from Nonroad Diesel Engines," EPA420-R-03-008, April 2003. This document is available at <http://www.epa.gov/nonroad/>. A copy of this document can also be found in Docket No. A-2001-28.

⁶⁰ *Acid Rain: Emissions Trends and Effects in the Eastern United States*, U.S. General Accounting Office, March, 2000 (GAO/RCED-00-47). A copy of this document is available in Docket No. OAR 2002-0030.

⁶¹ *Acid Deposition Standard Feasibility Study: Report to Congress*, EPA 430R-95-001a, October, 1995. A copy of this document is available in Docket No. OAR-2002-0030.

increased growth can cause numerous adverse ecological effects and economic impacts, including nuisance algal blooms, dieback of underwater plants due to reduced light penetration, and toxic plankton blooms. Algal and plankton blooms can also reduce the level of dissolved oxygen, which can also adversely affect fish and shellfish populations.

In 1999, NOAA published the results of a five year national assessment of the severity and extent of estuarine eutrophication. An estuary is defined as the inland arm of the sea that meets the mouth of a river. The 138 estuaries characterized in the study represent more than 90 percent of total estuarine water surface area and the total number of U.S. estuaries. The study found that estuaries with moderate to high eutrophication conditions represented 65 percent of the estuarine surface area. Eutrophication is of particular concern in coastal areas with poor or stratified circulation patterns, such as the Chesapeake Bay, Long Island Sound, or the Gulf of Mexico. In such areas, the "overproduced" algae tends to sink to the bottom and decay, using all or most of the available oxygen and thereby reducing or eliminating populations of bottom-feeder fish and shellfish, distorting the normal population balance between different aquatic organisms, and in extreme cases causing dramatic fish kills.

Severe and persistent eutrophication often directly impacts human activities. For example, losses in the nation's fishery resources may be directly caused by fish kills associated with low dissolved oxygen and toxic blooms. Declines in tourism occur when low dissolved oxygen causes noxious smells and floating mats of algal blooms create unfavorable aesthetic conditions. Risks to human health increase when the toxins from algal blooms accumulate in edible fish and shellfish, and when toxins become airborne, causing respiratory problems due to inhalation. According to the NOAA report, more than half of the nation's estuaries have moderate to high expressions of at least one of these symptoms—an indication that eutrophication is well developed in more than half of U.S. estuaries.

In recent decades, human activities have greatly accelerated nutrient inputs, such as nitrogen and phosphorous, causing excessive growth of algae and leading to degraded water quality and associated impairments of freshwater and estuarine resources for human uses.⁶² Since 1970, eutrophic conditions

worsened in 48 estuaries and improved in 14. In 26 systems, there was no trend in overall eutrophication conditions since 1970.⁶³ On the New England coast, for example, the number of red and brown tides and shellfish problems from nuisance and toxic plankton blooms have increased over the past two decades, a development thought to be linked to increased nitrogen loadings in coastal waters. Long-term monitoring in the U.S., Europe, and other developed regions of the world shows a substantial rise of nitrogen levels in surface waters, which are highly correlated with human-generated inputs of nitrogen to their watersheds.

Between 1992 and 1997, experts surveyed by National Oceanic and Atmospheric Administration (NOAA) most frequently recommended that control strategies be developed for agriculture, wastewater treatment, urban runoff, and atmospheric deposition.⁶⁴ In its Third Report to Congress on the Great Waters, EPA reported that atmospheric deposition contributes from 2 to 38 percent of the nitrogen load to certain coastal waters.⁶⁵ A review of peer reviewed literature in 1995 on the subject of air deposition suggests a typical contribution of 20 percent or higher.⁶⁶ Human-caused nitrogen loading to the Long Island Sound from the atmosphere was estimated at 14 percent by a collaboration of Federal and State air and water agencies in 1997.⁶⁷ The National Exposure Research Laboratory, U.S. EPA, estimated based on prior studies that 20 to 35 percent of the nitrogen loading to the Chesapeake Bay is attributable to atmospheric

copy of this document is available in Docket No. OAR 2002-0030.

⁶³ *Deposition of Air Pollutants to the Great Waters, Third Report to Congress*, June, 2000. Great Waters are defined as the Great Lakes, the Chesapeake Bay, Lake Champlain, and coastal waters. The first report to Congress was delivered in May, 1994; the second report to Congress in June, 1997. A copy of this document is available in Docket No. OAR 2002-0030.

⁶⁴ Bricker, Suzanne B., et al., *National Estuarine Eutrophication Assessment, Effects of Nutrient Enrichment in the Nation's Estuaries*, National Ocean Service, National Oceanic and Atmospheric Administration, September, 1999. A copy of this document is available in Docket No. OAR 2002-0030.

⁶⁵ *Deposition of Air Pollutants to the Great Waters, Third Report to Congress*, June, 2000. A copy of this document is available in Docket No. OAR 2002-0030.

⁶⁶ Valigura, Richard, et al., *Airsheds and Watersheds II: A Shared Resources Workshop*, Air Subcommittee of the Chesapeake Bay Program, March, 1997. Available in Docket A-99-06, Document No. IV-G-144.

⁶⁷ *The Impact of Atmospheric Nitrogen Deposition on Long Island Sound*, The Long Island Sound Study, September, 1997. A copy of this document is available in Docket No. OAR-2002-0030.

deposition.⁶⁸ The mobile source portion of atmospheric NO_x contribution to the Chesapeake Bay was modeled at about 30 percent of total air deposition.⁶⁹

Deposition of nitrogen from aircraft engines contributes to elevated nitrogen levels in waterbodies. The NO_x reductions from the proposed standards would help reduce the airborne nitrogen deposition that contributes to eutrophication of watersheds, particularly in aquatic systems where atmospheric deposition of nitrogen represents a significant portion of total nitrogen loadings.

3. Plant Damage From Ozone

Ground-level ozone can also cause adverse welfare effects. Specifically, ozone enters the leaves of plants where it interferes with cellular metabolic processes. This interference can be manifest either as visible foliar injury from cell injury or death, and/or as decreased plant growth and yield due to a reduced ability to produce food. With fewer resources, the plant reallocates existing resources away from root storage, growth and reproduction toward leaf repair and maintenance. Plants that are stressed in these ways become more susceptible to disease, insect attack, harsh weather and other environmental stresses. Because not all plants are equally sensitive to ozone, ozone pollution can also exert a selective pressure that leads to changes in plant community composition.

Since plants are at the center of the food web in many ecosystems, changes to the plant community can affect associated organisms and ecosystems (including the suitability of habitats that support threatened or endangered species and below ground organisms living in the root zone). Given the range of plant sensitivities and the fact that numerous other environmental factors modify plant uptake and response to ozone, it is not possible to identify threshold values above which ozone is toxic and below which it is safe for all plants. However, in general, the science suggests that ozone concentrations of 0.10 ppm or greater can be phytotoxic to a large number of plant species, and can produce acute foliar injury responses, crop yield loss and reduced biomass production. Ozone concentrations below 0.10 ppm (0.05 to 0.09 ppm) can produce these effects in more sensitive plant species, and have the potential over a longer duration of

⁶⁸ Dennis, Robin L., *Using the Regional Acid Deposition Model to Determine the Nitrogen Deposition Airshed of the Chesapeake Bay Watershed*, SETAC Technical Publications Series, 1997.

⁶⁹ *Ibid.*

⁶² *Deposition of Air Pollutants to the Great Waters, Third Report to Congress*, June, 2000. A

creating chronic stress on vegetation that can lead to effects of concern such as reduced plant growth and yield, shifts in competitive advantages in mixed populations, and decreased vigor leading to diminished resistance to pests, pathogens, and injury from other environmental stresses.

Studies indicate that these effects described here are still occurring in the field under ambient levels of ozone. The economic value of some welfare losses due to ozone can be calculated, such as crop yield loss from both reduced seed production (e.g., soybean) and visible injury to some leaf crops (e.g., lettuce, spinach, tobacco) and visible injury to ornamental plants (i.e., grass, flowers, shrubs), while other types of welfare loss may not be fully quantifiable in economic terms (e.g., reduced aesthetic value of trees growing in Class I areas).

As discussed earlier, aircraft engine emissions of NO_x contribute to ozone. The proposed standards would aid in the reduction of ozone and, therefore, help reduce crop damage and stress from ozone on vegetation.

4. Visibility

The secondary PM NAAQS is designed to protect against adverse welfare effects which includes visibility impairment. In 1997, EPA established the secondary PM_{2.5} NAAQS as equal to the primary (health-based) NAAQS of 15 µg/m³ (based on a 3-year average of the annual mean) and 65 µg/m³ (based on a 3-year average of the 98th percentile of the 24-hour average value) (62 FR 38669, July 18, 1997). EPA concluded that PM_{2.5} causes adverse effects on visibility in various locations, depending on PM concentrations and factors such as chemical composition and average relative humidity. In 1997, EPA demonstrated that visibility impairment is an important effect on public welfare and that unacceptable visibility impairment is experienced throughout the U.S., in multi-state regions, urban areas, and remote federal Class I areas. In many cities having annual mean PM_{2.5} concentrations exceeding annual standard, improvements in annual average visibility resulting from the attainment of the annual PM_{2.5} standard are expected to be perceptible to the general population. Based on annual mean monitored PM_{2.5} data, many cities in the Northeast, Midwest, and Southeast as well as Los Angeles would be expected to experience perceptible improvements in visibility if the PM_{2.5} annual standard were attained.

Furthermore, in setting the PM_{2.5} NAAQS, EPA acknowledged that levels of fine particles below the NAAQS may

also contribute to unacceptable visibility impairment and regional haze problems in some areas, and section 169 of the Act provides additional authorities to remedy existing impairment and prevent future impairment in the 156 national parks, forests and wilderness areas labeled as mandatory Federal Class I areas (62 FR 38680–81, July 18, 1997).

Visibility can be defined as the degree to which the atmosphere is transparent to visible light.⁷⁰ Fine particles with significant light-extinction efficiencies include organic matter, sulfates, nitrates, elemental carbon (soot), and soil. Size and chemical composition of particles strongly affects their ability to scatter or absorb light. Nitrates typically contribute 1 to 6 percent of average light extinction on haziest days in rural Eastern U.S. locations.⁷¹

Visibility is important because it directly affects people's enjoyment of daily activities in all parts of the country. Individuals value good visibility for the well-being it provides them directly, both in where they live and work, and in places where they enjoy recreational opportunities. Visibility is also highly valued in significant natural areas such as national parks and wilderness areas, because of the special emphasis given to protecting these lands now and for future generations.

To quantify changes in visibility, we compute a light-extinction coefficient, which shows the total fraction of light that is decreased per unit distance. Visibility can be described in terms of visual range or light extinction and is reported using an indicator called deciview.⁷² In addition to limiting the

distance that one can see, the scattering and absorption of light caused by air pollution can also degrade the color, clarity, and contrast of scenes.

In addition, visibility impairment can be described by its impact over various periods of time, by its source, and the physical conditions in various regions of the country. Visibility impairment can be said to have a time dimension in that it might relate to short-term excursions or to longer periods (e.g., worst 20 percent of days and annual average levels). Anthropogenic contributions account for about one-third of the average extinction coefficient in the rural West and more than 80 percent in the rural East. In the Eastern U.S., reduced visibility is mainly attributable to secondarily formed particles, particularly those less than a few micrometers in diameter. While secondarily formed particles still account for a significant amount in the West, primary emissions contribute a larger percentage of the total particulate load than in the East.

Furthermore, it is important to note that even in those areas with relatively low concentrations of anthropogenic fine particles, such as the Colorado Plateau, small increases in anthropogenic fine particulate concentrations can lead to significant decreases in visual range. This is one of the reasons mandatory Federal Class I areas have been given special consideration under the Clean Air Act.⁷³

Taken together with other programs, reductions from this proposal would help to improve visibility across the nation, including mandatory Federal Class I areas.

C. Other Criteria Pollutants Affected by This Proposed Rule

The standards being proposed today would also help reduce levels of nitrogen dioxide (NO₂), for which NAAQS have been established. Currently, every area in the United States has been designated to be in attainment with the NO₂ NAAQS.

IV. Description of Action

Under the authority of section 231 of the CAA, EPA today proposes to adopt standards equivalent to ICAO's February 1999 NO_x emission standards (these NO_x standards were adopted at CAEP/4 in 1998 and approved by the ICAO Council in 1999) and March 1997 test

decibel scale for sound. A deciview of 0 represents pristine conditions. Under many scenic conditions, a change of 1 deciview is considered perceptible by the average person.

⁷³ The Clean Air Act designates 156 national parks and wilderness areas as mandatory Federal Class I areas for visibility protection.

⁷⁰ National Research Council, 1993. Protecting Visibility in National Parks and Wilderness Areas. National Academy of Sciences Committee on Haze in National Parks and Wilderness Areas. National Academy Press, Washington, DC. This book can be viewed on the National Academy Press Website at <http://www.nap.edu/books/0309048443/html/>. See also U.S. EPA Air Quality Criteria Document for Particulate Matter (1996) (available on the internet at <http://cfpub.epa.gov/ncea/cfm/partmatt.cfm>) and Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information. These documents can be found in Docket A-99-06, Documents No. II-A-23 and IV-A-130-32.

⁷¹ US EPA Trends Report 2001. This document is available on the internet at <http://www.epa.gov/airtrends/>. A copy of this document is available in Docket No. OAR 2002-0030.

⁷² Visual range can be defined as the maximum distance at which one can identify a black object against the horizon sky. It is typically described in miles or kilometers. Light extinction is the sum of light scattering and absorption by particles and gases in the atmosphere. It is typically expressed in terms of inverse megameters (Mm⁻¹), with larger values representing worse visibility. The deciview metric describes perceived visual changes in a linear fashion over its entire range, analogous to the

procedure amendments. Today's proposed emission standards and test procedure amendments apply to commercial aircraft engines; no general aviation or military engines are covered by today's proposal. The commercial aircraft engines subject to today's proposed NO_x standards are those gas turbine engines that are newly certified (and designed) after the effective date of the proposed regulations. (Newly manufactured or already certified engines built after the effective date of the proposed regulations would not have to meet these standards.) For the sake of consistency and harmonization, the effective dates below for the proposed NO_x standards are identical with those of the ICAO 1999 NO_x standards. The proposed NO_x emission standards, test procedure amendments, and their effective dates are described below.

A. What Emission Standards Are Under Consideration?

As discussed earlier in sections II and III of today's notice, section 231(a)(2)(A) of the CAA authorizes EPA to establish emission standards for aircraft engine emissions " * * * which in [her] judgment causes, or contributes to, air pollution which may reasonably be anticipated to endanger public health or welfare." The Administrator may revise such standards from "time to time." CAA section 231(b) requires that any emission standards provide sufficient lead time "to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period."

Today's rule proposes near-term standards that would go into effect in 2004 to ensure future engines do not jeopardize recent or past technology gains. These standards are equivalent to the CAEP/4 NO_x international consensus emissions standards for aircraft engines adopted by ICAO's CAEP in 1998.⁷⁴ EPA intends to promulgate these standards by January 2004 in order to be consistent with U.S. obligations under ICAO. At the same time, EPA anticipates establishing more stringent NO_x standards in the future. EPA will participate at CAEP/6 (sixth meeting of CAEP), which is scheduled in February 2004, to establish more stringent international consensus emission standards for aircraft engines. Such standards would likely be a

central consideration in a future EPA regulation of aircraft engine emissions.

We believe this two-step approach is the most appropriate means to address emissions from aircraft engines in this rulemaking. It would codify current practice, with no significant lead time, as a near-term approach.⁷⁵ EPA has authority to revise emission standards from "time to time". EPA intends to address more stringent emission standards requiring more lead time in a future rulemaking (see section IV.A.5. for further discussion of future standards).

1. Today's Proposed NO_x Standards

EPA proposes to adopt standards equivalent to ICAO's 1999 NO_x emission standards for newly certified aircraft gas turbine engines (turbofan and turbojet engines) of rated thrust or output greater than 26.7 kilonewtons (kN) with compliance dates as follows:⁷⁶

For engines of a type or model of which that date of manufacture of the first individual production model was after December 31, 2003:

(a) for engines with a pressure ratio of 30 or less:

(i) for engines with a maximum rated output of more than 89.0 kN:

$$\text{NO}_x = (19 + 1.6(\text{rated pressure ratio}))g/kN(\text{rated output})$$

(ii) for engines with a maximum rated output of more than 26.7 kN but not more than 89.0 kN:

$$\text{NO}_x = (37.572 + 1.6(\text{rated pressure ratio}) - 0.2087(\text{rated output}))g/kN(\text{rated output})$$

(b) for engines with a pressure ratio of more than 30 but less than 62.5:

(i) for engines with a maximum rated output of more than 89.0 kN:

$$\text{NO}_x = (7 + 2.0(\text{rated pressure ratio}))g/kN(\text{rated output})$$

(ii) for engines with a maximum rated output of more than 26.7 kN but not more than 89.0 kN:

$$\text{NO}_x = (42.71 + 1.4286(\text{rated pressure ratio}) - 0.4013(\text{rated output}) + 0.00642(\text{rated pressure ratio} \times \text{rated output}))g/kN(\text{rated output})$$

(c) for engines with a pressure ratio of 62.5 or more:

$$\text{NO}_x = (32 + 1.6(\text{rated pressure ratio}))g/kN(\text{rated output})$$

The NO_x emission standards presented above are equivalent to the ICAO NO_x standards that have an

⁷⁵ As described later, more information and greater lead time would be necessary to require more stringent standards.

⁷⁶ This proposal includes standards for low-, mid-, and high-thrust engines (see below for further discussion of the different standards based on the thrust of the engines).

implementation date of December 31, 2003.⁷⁷

2. Proposed NO_x Standards for Newly Certified Mid- and High-Thrust Engines

EPA is proposing to adopt NO_x standards for newly certified mid- and high-thrust engines (those engines designed and certified after the effective date of the proposed regulations, which have a rated output or thrust greater than 89 kN) that generally represent about a 16 percent reduction (or increase in stringency) from the existing standard. (See section IV.A.1(a)(i) and IV.A.1(b)(i) above for the standards for mid- and high-thrust engines.) More specifically, at a rated pressure ratio of 30 the proposed NO_x standards represent a 16 percent reduction from the existing standard. At rated pressure ratios of 10 and 20, the proposed standards correspond to 27 and 20 percent reductions, respectively. In addition, at rated pressure ratios of 40 and 50, the proposed NO_x standards signify 9 and 4 percent reductions, respectively. Also, the proposed and existing standards are equivalent at a rated pressure ratio of 62.5. See Figure IV.B-1 in section IV.B. for a comparison of the proposed NO_x standards (equivalent to CAEP/4 standards) to the existing standards (equivalent to CAEP/2 standards).

3. Proposed NO_x Standards for Newly Certified Low-Thrust Engines

For newly certified low-thrust engines (engines with a thrust or rated output of more than 26.7 kN but not more than 89.0 kN), EPA is today proposing to adopt near-term NO_x standards that are different than the standards proposed for mid- and high-thrust engines (engines with thrust greater than 89.0 kN).⁷⁸ In addition to rated pressure ratio, the proposed standards for low-

⁷⁷ ICAO's CAEP/4 NO_x standards became effective July 19, 1999, and applicable as of November 4, 1999. December 31, 2003 is the implementation date for these standards. However, for the purpose of this Notice the effective date is considered the implementation date. (ICAO, "Aircraft Engine Emissions," International Standards and Recommended Practices, Environmental Protection, Annex 16, Volume II, Second Edition, July 1993—Amendment 4, July 19, 1999.)

⁷⁸ Today's proposed NO_x standards for low thrust or small engines specify that engines with a rated output or thrust at 26.7 kN meet the existing standard, and engines with a rated output at 89 kN meet the proposed (or CAEP/4) standards. For engines with rated outputs or thrust levels between 26.7 and 89 kN, a linear interpolation was made between the low range of the existing standard and the high range of the proposed standard based upon the rated output to determine the proposed NO_x limits for such engines. Thus, thrust dependent standards are being proposed for engines with rated output or thrust between 26.7 kN and 89 kN.

⁷⁴ ICAO, CAEP, Fourth Meeting, Montreal, Quebec, April 6-8, 1998, Report, Document 9720, CAEP/4. Copies of this document can be obtained from the ICAO Web site located at <http://www.icao.int>.

thrust engines would also be dependent on an engine's thrust or rated output.⁷⁹ (See section IV.A.1(a)(ii) and IV.A.1(b)(ii) for a description of these different standards.) For example, at a rated pressure ratio of 30 and a thrust of 58 kN (thrust level in the middle of 26.7 kN and 89 kN), these proposed standards are an 8 percent reduction (or increase in stringency) from the existing standard compared to a 16 percent reduction for the proposed standards for mid- and high-thrust engines.⁸⁰

The existing standards were not set at a stringency level that created a need for low-thrust engines to have different requirements, but at the level of NO_x stringency proposed today different requirements are considered necessary for such engines. Due to their physical size, it is difficult to apply the best NO_x reduction technology to low thrust or small engines. The difficulty increases progressively as size is reduced (from around 89 kN).⁸¹ For example, the relatively small combustor space and section height of these engines creates constraints on the use of low NO_x fuel staged combustor concepts which inherently require the availability of greater flow path cross-sectional area than conventional combustors.⁸² Also, fuel staged combustors need more fuel injectors, and this need is not compatible with the relatively lower total fuel flows of lower thrust engines. (Reductions in fuel flow per nozzle are difficult to attain without having clogging problems due to the small sizes of the fuel metering ports.) In addition, lower thrust engine combustors have an inherently greater liner surface-to-

combustion volume ratio, and this requires increased wall cooling air flow. Thus, less air would be available to obtain acceptable turbine inlet temperature distribution and for emissions control.⁸³ Since the difficulties increase progressively as engine thrust size is reduced, EPA believes it would be appropriate to make a graded change in stringency of the proposed NO_x standards for low-thrust engines.

4. Rationale of Proposed NO_x Standards for Newly Certified Low-, Mid-, and High-Thrust Engines

The proposed standards for low-, mid-, and high-thrust engines, which are equivalent to the CAEP/4 standards, ensure that new engine designs would incorporate the existing combustor technology and would not perform worse than today's current engines. EPA intends to promulgate these standards by January 2004 in order to be consistent with U.S. obligations under ICAO. (See section II.B for a discussion of the obligation of ICAO's participating nations). At this time, there is not sufficient lead time to require more stringent emission standards than the CAEP/4 NO_x emission standards by January 2004. As discussed later in section IV.A.5 for future standards, we are deferring action on more stringent NO_x standards because pursuant to section 231(b) of the CAA we need more time to better understand the cost of compliance with such standards, and additional cost data is expected to be available from CAEP/6 in February 2004 (see section IV.A.5 for further discussion regarding lead time).

EPA believes that the proposed standards would not impose any additional burden on manufacturers, because manufacturers are already designing new engines to meet the ICAO international consensus standards by 2004 (see section VII of today's action for further discussion of regulatory impact). Even though the U.S. did not immediately adopt the ICAO NO_x standards after 1999, engine manufacturers have continued to make progress in reducing these emissions. Today's proposed standards are aimed at assuring that this progress is not reversed in the future.

5. Future NO_x Standards for Newly Certified Low-, Mid-, and High-Thrust Engines

More stringent standards for low-, mid-, and high-thrust engines will be necessary in the future. As discussed earlier in section III, the growth in aircraft emissions is projected to occur at a time when other mobile source categories are reducing emissions.⁸⁴ The 1999 EPA study of commercial aircraft activity in ten cities projected that the aircraft NO_x emissions would double in some of these cities by 2010, and the aircraft component of the regional mobile source NO_x emissions in the ten cities would grow from a range of 1 to 4 percent that existed in 1990 to a range of 2 to 10 percent in 2010.⁸⁵ (As indicated earlier, the above projections were made prior to the tragic events of September 11, 2001, and the subsequent economic downturn. A January 2003 report by the Department of Transportation indicated that the combination of the September 11, 2001 terrorist attacks and a cut-back in business travel had a significant and perhaps long-lasting effect on air traffic demand. However, the FAA expects the demand for air travel to recover, and then continue a long-term trend of annual growth in the United States.) More recently, as discussed earlier FAA reports that flights (or activity) of commercial air carriers will increase by 18 percent by 2010 and 45 percent by 2020.⁸⁶ Thus, based on these trends

⁷⁹ The proposed standards for mid- and high-thrust engines are dependent only on an engine's rated pressure ratio.

⁸⁰ Additional examples of the proposed standards for low-thrust engines in comparison to the proposed standards for mid- and high-thrust engines are provided below. At rated pressure ratios of 10 and 20 with a thrust of 58 kN, the proposed low-thrust engine standards are a 14 and 10 percent reduction from the existing standard, respectively. Whereas, at these same rated pressure ratios, the proposed standards for mid- and high-thrust engines are 27 and 20 percent reductions.

In addition, at rated pressure ratios of 40 and 50 with a thrust of 58 kN, these low-thrust engine standards signify a 5 and 2 percent reduction from the existing standard, respectively. In comparison, at these same rated pressure ratios, the proposed standards for mid- and high-thrust engines are 9 and 4 percent reductions.

⁸¹ ICAO/CAEP, Report of Third Meeting, Montreal, Quebec, December 5–15, 1995, Document 9675, CAEP/3.

⁸² "The burner section of an aircraft engine, which contains the combustion chamber, burns a mixture of fuel and air, and delivers the resulting gases to the turbine at a temperature which will not exceed the allowable limit at the turbine inlet." (United Technologies Pratt and Whitney, "The Aircraft Gas Turbine Engine and Its Operation," August 1998.)

⁸³ ICAO/CAEP Working Group 3 (Emissions), "Combined Report of the Certification and Technology Subgroups," section 2.3.6.1, Presented by the Chairman of the Technology Subgroup, Third Meeting, Bonn, Germany, June 1995. A copy of this paper can be found in Docket OAR-2002-0030.

⁸⁴ The projected growth in aircraft emissions is not simply from the number of operations, but it could also be attributed to the change in the types of aircraft being operated. For example, regional aircraft activity is growing (regional aircraft are generally referred to as those aircraft with more than 19 but fewer than 100 seats—regional jets and turboprops). In the U.S., traffic flown by regional airlines increased about 20 percent in 1999 and is expected to grow approximately 7 percent annually during the next ten years, compared to 4 to 6 percent for the major airlines. In addition, regional jets comprised about 25 percent of the regional aircraft fleet in 2000, up from only 4.2 percent in 1996, and their fraction of the fleet is expected to increase to nearly 50 percent by 2011. Regional aircraft are 40 to 60 percent less fuel efficient compared to larger narrow- and wide-body aircraft, and regional jets are 10 to 60 percent less fuel efficient than turboprop aircraft. However, fuel costs have less of an effect on the operating costs of regional aircraft compared to large aircraft. In addition, regional jets have historically operated at higher load factors than turboprops due to their popularity with travelers. (R. Babikian, S. P. Lukachko and I. A. Waitz, "Historical Fuel Efficiency Characteristics of Regional Aircraft from Technological, Operational, and Cost Perspectives," *Journal of Air Transport Management*, Volume 8, No. 6, pp. 389–400, Nov. 2002).

⁸⁵ U.S. EPA, "Evaluation of Air Pollutant Emissions from Subsonic Commercial Jet Aircraft," April 1999, EPA420-R-99-013. This study is available at <http://www.epa.gov/otaq/aviation.htm>. It can also be found in Docket No. OAR-2002-0030.

⁸⁶ The flight forecast data is based on FAA's Terminal Area Forecast System (TAFS). TAFS is the

more stringent NO_x standards than the proposed standards are needed in the future to reduce aircraft NO_x emissions in nonattainment areas.

Further stringency of the NO_x standards would reduce the expected growth in commercial aircraft emissions. The importance of controlling aircraft emissions has grown in many areas (especially areas not meeting the 1-hour and 8-hour ozone NAAQS) as controls on other sources become more stringent and attainment of the NAAQS's has still not been achieved. (Many airports in the U.S. are located in nonattainment areas.⁸⁷) As activity increases, aircraft would emit increasing amounts of NO_x in many nonattainment areas, and thus, aircraft emissions would further aggravate the problems in these areas (either by emitting pollutants directly within a nonattainment area or by contributing to regional transport emissions in an area upwind of a nonattainment area). More stringent aircraft engine NO_x standards would assist in alleviating these problems in nonattainment areas, and they would aid in preventing future concerns in areas currently designated as attainment (or maintenance) areas. In addition, attainment or maintenance of the NAAQS requires that aircraft engines be subject to a program of control compatible with their significance as pollution sources.

EPA, therefore, is considering more stringent future standards, beyond today's proposed standards. Leading up to CAEP/6 in February 2004, one of the objectives of CAEP (and/or the international aviation community) is to consider more stringent aircraft engine standards than CAEP/4 standards for all

official forecast of aviation activity at FAA facilities. This includes FAA-towered airports, federally-contracted towered airports, nonfederally towered airports, and many non-towered airports. For detailed information on TAFS and the air carrier activity forecasts see the following FAA Web site: <http://www.apo.data.faa.gov/jaatafall.HTM>. As of May 1, 2003, the aviation forecasts contained in TAFS for Fiscal Years 2002–2020 included the impact of the terrorists' attacks of September 11, 2001 and the recent economic downturn. However, these projections did not fully reflect the ongoing structural changes occurring within the aviation industry. A copy of the May 1, 2003 forecast summary report for air carrier activity can be found in Docket No. OAR–2002–0030.

⁸⁷ For information on the geographic location of airports, see the following U.S. Department of Transportation (Bureau of Transportation Statistics) Web site: <http://www.bts.gov/oai>. The report or database provided on the website entitled, "Airport Activity Statistics of Certificated Air Carriers: Summary Tables 2000," lists airports by community. In addition, see the following EPA website for information on nonattainment areas for criteria pollutants: <http://www.epa.gov/oar/oaqps/greenbk>.

gaseous emissions, especially NO_x.⁸⁸ ICAO CAEP working groups are currently assessing the technological feasibility, economic reasonableness, and environmental benefit of imposing more stringent NO_x emissions standards for aircraft engines beyond that which will become effective in 2004 (CAEP/4 standards). Options being considered range from 5 to 30 percent more stringent with an effective date as early as 2008 to 2012 (these options are accompanied by more stringent standards for low-thrust engines).⁸⁹ Based on the results of this assessment, a proposal for more stringent NO_x standards is expected to be made at CAEP/6.⁹⁰ (No changes to the standards of other pollutants, hydrocarbons and carbon monoxide, are anticipated.) Activity is also underway to identify and assess the potential for long-term technology goals to be established for further emissions reductions.^{91 92} The aim of the goal setting activity is to complement the ICAO CAEP standard setting process with information to aid the engine and airframe manufacturer's design process. The goals are expected to take into account the results of recently completed emissions reduction technology programs such as those conducted by National Aeronautics and Space Administration (NASA) and the European Commission and the timeline necessary to carry those technologies

⁸⁸ ICAO, CAEP, Fifth Meeting, Montreal, Quebec, January 1–17, 2001, "Report on Agenda Item 4," CAEP/5–WP/86, January 17, 2001. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

⁸⁹ ICAO, CAEP, Steering Group Meeting, Paris, France, September 10–13, 2002, "Summary of Discussions and Decisions of the Second Meeting of the Steering Group," September 11, 2002, CAEP–SG2002–SD/2. A copy of this paper can be found in Docket OAR–2002–0030. Since this paper was written, the working groups have also decided to consider the range of stringency options for an effective date of 2008.

⁹⁰ ICAO, CAEP, Steering Group Meeting, Paris, France, September 10–13, 2002, "Summary of Discussions and Decisions of the First Meeting of the Steering Group," September 10, 2002, CAEP–SG2002–SD/1. A copy of this paper can be found in Docket OAR–2002–0030.

⁹¹ ICAO, CAEP, Fifth Meeting, Montreal, Quebec, January 1–17, 2001, "Report on Agenda Item 4," CAEP/5–WP/86, January 17, 2001. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

⁹² For the purpose of setting long-term technology goals, activity on the below tasks was initiated after CAEP/5 in 2001, and it is expected to continue beyond CAEP/6.

(a) characterize emissions performance of future technologies being pursued under national and international research programs, including technology readiness;

(b) develop methodologies for quantifying aviation emissions inventories;

(c) develop forecasts of emission trends both locally and globally; and

(d) examine how such goals might be applied within the current regulatory regime.

from the research phase through commercialization.⁹³ EPA is currently working with FAA and CAEP working groups (as described in section V) in the evaluation of NO_x stringency options for CAEP/6 and the potential for long-term technology goals.

Manufacturers should be able to achieve additional reductions with more lead time than is provided by today's proposal. After CAEP/6, we would assess whether or not the new international consensus and longer-term standards (which are expected to be adopted) would be stringent enough to protect the U.S. public health and welfare. If so, we would propose to adopt the CAEP/6 NO_x standards soon thereafter. EPA (or the U.S.) retains the discretion to adopt more stringent standards in the future if the international consensus standards ultimately prove insufficient to protect U.S. air quality.

Deferring consideration of more stringent future standards until after CAEP/6 would allow us to obtain important additional information on the costs of such standards.⁹⁴ As described earlier in this notice, section 231 of the CAA authorizes EPA from "time to time" to revisit emission standards, and it requires that any standards' effective dates permit the development of necessary technology, giving appropriate consideration to the cost. We are not proposing more stringent NO_x standards today primarily because we need more time to better understand the cost of compliance of such standards, and additional cost data is expected to be available from CAEP/6 in February 2004. Producing (and/or developing) new engines or engine technologies requires significant financial investments from engine manufacturers, which takes time to recoup (the amount of time depends upon sales of engines, replacement parts, etc.). As discussed earlier, CAEP working groups are currently analyzing the costs and emission benefits (taking into account lead time) for the options of further NO_x stringency (beyond the CAEP/4 standards) being considered for CAEP/6.⁹⁵ After evaluating such

⁹³ ICAO, CAEP, Fourth Meeting, Montreal, Quebec, April 6–8, 1998, Report, Document 9720, CAEP/4, see Appendix A to the Report on Agenda Item 4 (page 4–A–1). Copies of this document can be obtained from ICAO (<http://www.icao.int>).

⁹⁴ For low-thrust engines, deferring regulatory action on more stringent future standards until after CAEP/6 would also enable us to obtain additional information on the technological feasibility of such standards.

⁹⁵ Specifically, the Forecasting and Economic Analysis Support Group (FESG) is conducting an

Continued

information, we would then be better situated to make decisions on an appropriate level of stringency and implementation timing that maximizes emission reductions from aircraft engines, taking into consideration cost.

In addition, if we address more stringent future standards in accordance with CAEP/6 action, we would have the benefits of harmonizing with international standards.⁹⁶ Due to the international nature of the aviation industry, setting NO_x standards at the appropriate level to meet U.S. air quality needs through international consensus provides the potential for greater environmental benefits. Aircraft and aircraft engines are international commodities, and they are designed and built to meet international standards. Adoption of international standards ensures emission reductions from domestic and foreign aircraft in the U.S. In addition, international consensus standards lead to air quality benefits in the U.S. and throughout the world.

B. Already Certified, Newly Manufactured Engines

Under current rules, the proposed NO_x standards would not apply to already certified, newly manufactured engines (in-production engines or engines built after the effective date of the proposed standards), and the rationale for not applying these standards to already certified low-, mid-, and high-thrust engines is discussed below. Nearly all already certified engines (94 percent of in-production engine models in the ICAO Aircraft Engine Exhaust Emissions Data Bank⁹⁷) currently meet or perform better than the standards we are

analysis of the costs and emission benefits for the further stringency options.

⁹⁶ As discussed earlier, the U.S. has an obligation to be compatible with the ICAO program if deemed appropriate.

⁹⁷ International Civil Aviation Organization (ICAO), Aircraft Engine Exhaust Emissions Data Bank, July 2002. This data bank is available at <http://www.qinetiq.com/aircraft.html>. In addition, a copy of a table including data of engine NO_x emissions from the ICAO data bank and their margin to the proposed NO_x standards can be found in Docket OAR-2002-0030.

proposing to adopt today.⁹⁸ (See Figure IV.B-1 below for a comparison of the NO_x emission levels of current in-production engines to the CAEP/4 NO_x standards.)⁹⁹ At the time the CAEP/4 NO_x standards were adopted in 1998, all but 11 in-production engines and 5 newly designed engine models (these 5 engines were in the design and development process in 1998) had NO_x emission levels that would perform better than the CAEP/4 standards.¹⁰⁰

⁹⁸ 116 out of 124 (94 percent) engine models that are currently in production perform better than the CAEP/4 NO_x standards. The 8 engine models (which are mid- and high-thrust engines) that are not achieving the CAEP/4 NO_x standards are from three different Pratt and Whitney (PW) engine types or families (engines and their thrust variants with the same build standard). These engines are the following: (1) JT8D-217C E-kit and JT8D-219 E-kit; (2) PW4077D, PW4084D, and PW4090; and (3) PW4164, PW4168, and PW4168A. (See Figure IV.B-1 below that specifically shows these 8 in-production models in relation to the CAEP/4 or proposed NO_x standards.) For the year 2000, these 8 engine models were found on approximately 751 out of 20,137 (3.7 percent) aircraft owned by U.S. carriers and accounted for approximately 1,541,172 out of 11,505,063 (13.4 percent) of U.S. domestic flights.

(The above reference for the fleet fraction is BACK Aviation Solutions, http://www.backaviation.com/Information_Services/default.htm.

The domestic flight information is based on SAGE, the System for Assessing Aviation Emissions. SAGE is an FAA model that estimates aircraft emissions through the full flight profile using non-proprietary input data, such as BACK, FAA's Enhanced Traffic Management System (ETMS), and the Official Airline Guide (OAG). The year 2000 air traffic movements database portion of SAGE was used to estimate the number of flights using the subject engines.)

⁹⁹ For Figure IV.B-1, the Allison, Rolls-Royce, and Textron Lycoming engines with rated pressure ratios less than 20 and NO_x perform better than the standards, since there are different CAEP/4 NO_x standards for these low-thrust engines (see section IV.A.3 for further discussion of NO_x standards for low thrust engines). (16 of the 124 engines, 13 percent of engine models in production, in Figure IV.B-1 and the ICAO Aircraft Engine Exhaust Emissions Data Bank are low-thrust engines—engines with thrust greater than 26.7 kN but not more than 89 kN.)

¹⁰⁰ ICAO, CAEP/4, Working Paper 4, "Economic Assessment of the EPG NO_x Stringency Proposal," March 12, 1998, Presented by the Chairman of Forecasting and Economic Analysis Support Group (FESG), Agenda Item 1: Review of proposals relating to NO_x emissions, including the amendment of Annex 16, Volume II, See Table 3.1

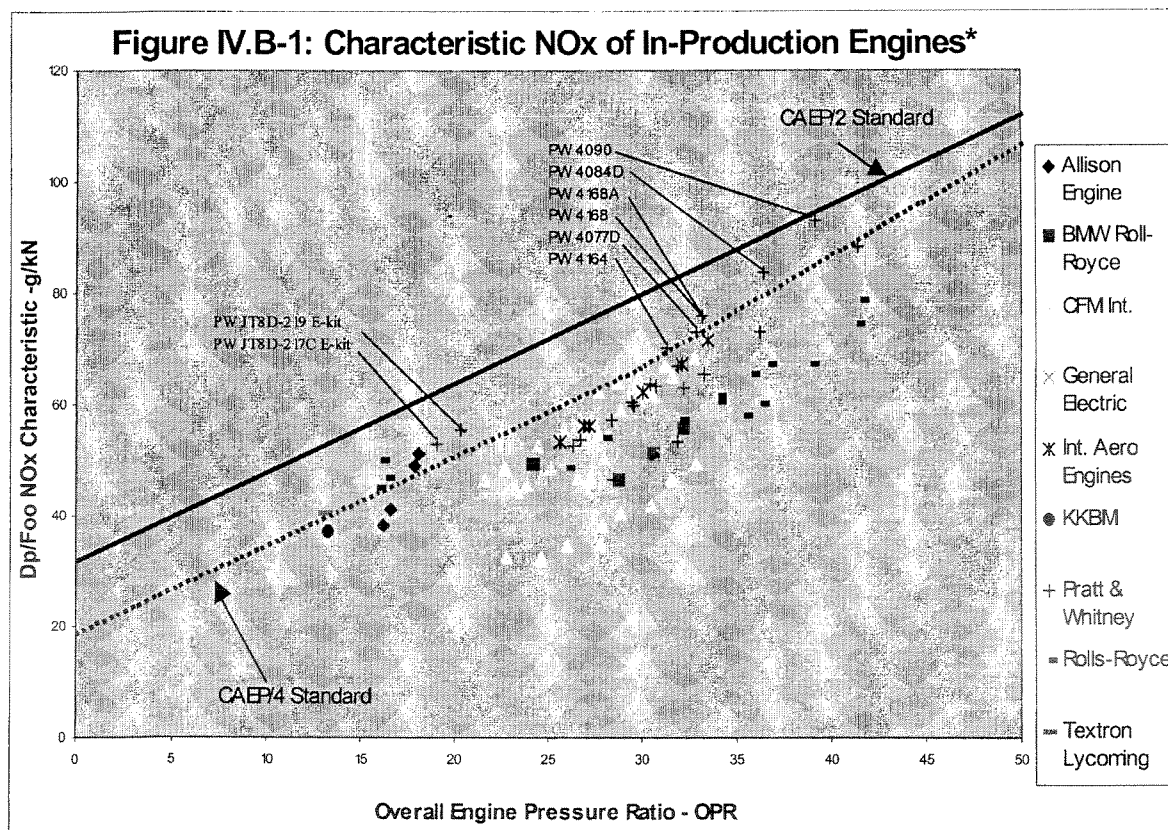
Based on a recent CAEP working group (specifically, the Forecasting and Economic Analysis Support Group—FESG) analysis of applying the CAEP/4 standards to already certified engines (at dates 2, 4, and 6 years after the implementation date for newly certified engines), from those 16 engine models identified in 1998 today there are only 4 already certified engine models or two engine families remaining that would not meet the CAEP/4 standards.¹⁰¹ The other engine models have either, through additional testing or modifications, been improved to meet the standards or the engines are no longer in-production.¹⁰² (There is only one remaining newly designed engine model—out of the five identified in 1998—that may be certified after 2003, and thus, it would need to meet the CAEP/4 or proposed standards for newly certified engines, which are effective beginning in 2004.)¹⁰³

of paper. A copy of this paper can be found in Docket OAR-2002-0030.

¹⁰¹ CAEP Steering Group Meeting, "FESG Economic Assessment of Applying a Production Cut-Off To the CAEP/4 NO_x Standard", Presented by the FESG Co-Rapporteurs, Paris, September 10-13, 2002 (CAEP-SG2002-WP/20, September 12, 2002). The remaining already certified engine models are the JT8D-217C, JT8D-219, PW4084D, and PW4090. A copy of this paper can be found in Docket OAR-2002-0030.

¹⁰² Only the first and second engine types of the three PW types described earlier would not meet the CAEP/4 NO_x standards if they were applied to newly manufactured or already certified engines. The PW4077D is a derated version of the PW4084D, and it is essentially considered the same engine. In addition, the PW4077D has a NO_x level that is 0.2 percent greater than the CAEP/4 standards. FESG rounded this margin to zero and considered the PW4077D to be meeting the NO_x levels of the CAEP/4 standards. The third engine type—PW4164, PW4168 and PW4168A engines—are now certified with the PW 4168 Technologically Affordable Low NO_x (Talon) II engine combustor technology, which performs significantly better than the CAEP/4 standards.

¹⁰³ The PW Canada growth engine is the one remaining newly designed engine model. The ICAO Aircraft Engine Exhaust Emissions Data Bank currently does not have emissions certification data for such an engine, and thus, we anticipate that the PW Canada growth engine would still be affected by the proposed standards. Yet, due to the CAEP/4 standards already established, we expect that PW Canada has already planned modifications for this engine or any other newly certified engines to meet today's proposed standards.



*89 out of 124 (72 percent) of the in-production engines have greater than 10 percent margin to the proposed (or CAEP/4) NO_x standards. 56 (45 percent) of the engines have more than 20 percent margin. 18 (15 percent) of the engines have greater than 30 percent margin.

The recent FESG analysis indicates that the environmental benefit (or NO_x emissions reduction) of applying the CAEP/4 NO_x standards to already certified engines, which would only affect these 4 remaining engines, would be very small. As mentioned earlier, the remaining four already certified (or in-production) engines that perform worse than the CAEP/4 or proposed standards are the following Pratt and Whitney (PW) mid- and high-thrust engines: JT8D-217C, JT8D-219, PW4084D, and PW4090. The in-production JT8D-217C and JT8D-219 engines could potentially apply to future supersonic business jets, and the aircraft application for PW4084D and 4090 engines would be the Boeing 777-200s and -300s. Since business jets have a very low utilization (about 100 to 200 annual departures per aircraft), the emission reductions from potential new JT8D-217C and JT8D-219 applications would be very small irregardless of the size of the supersonic business jet market. If the potential JT8D-217C and JT8D-219 supersonic

business jets were to capture the entire projected supersonic business jet market (200 to 400 aircraft over a 10 year period or 20 to 40 aircraft per year), the total estimated annual departures would be about 2,000 to 8,000. For the years 2005 and 2010, there are estimated to be from 23 to 27 million departures from the global passenger aircraft fleet (the potential supersonic business jet market could potentially be about .01 to .03 percent of these global fleet departures), so the resulting NO_x emission benefits would be very small.¹⁰⁴ In regard to Boeing 777 aircraft with PW4084D/4090 engines, the incremental departures for such aircraft are projected to be no greater than 0.1 percent per year (up to 25,500 departures in 2010); therefore, the resulting NO_x emissions reductions would also be considered very small. (The FESG assessment also showed that the costs of applying the CAEP/4 standards to already certified engines would be relatively small on an industry

¹⁰⁴ CAEP Steering Group Meeting, "FESG Economic Assessment of Applying a Production Cut-Off To the CAEP/4 NO_x Standard", Presented by the FESG Co-Rapporteurs, Paris, September 10-13, 2002 (CAEP-SG2002-WP/20, September 12, 2002). In particular, see Table 5.1 entitled, "Excerpt from FESG CAEP/5 Traffic and Fleet Mix Forecast." A copy of this paper can be found in Docket OAR-2002-0030.

wide basis.)¹⁰⁵ Consequently, we would expect there to be minimal environmental benefit to also apply the proposed and CAEP/4 NO_x standards for newly certified engines to already certified, newly manufactured engines for an effective date after 2003 (the implementation date of today's proposed standards is December 31, 2003).

Also, if an already certified engine design meets the standards that we are proposing today, then it is unlikely that either existing or future engine designs built to that design or type (derivatives or thrust variants with the same build standard) would not meet these standards. When design modifications are made to an existing engine type, then this engine type would likely need to be re-certified. A re-certified engine type would be required to comply with the CAEP/4 and new proposed NO_x standards.

For the remaining 4 engines (or two engine families) being built that do not meet the CAEP/4 standards, Pratt and Whitney has other in-production engine models (potentially derived versions or thrust variants of engines with the same

¹⁰⁵ The costs of applying CAEP/4 standards to already certified engines would impact just one engine manufacturer.

build standard) or replacement/alternative engines that perform better than the proposed NO_x standards and that are also similar in size and aircraft application.¹⁰⁶ For example, the PW 4098 engine would achieve the NO_x levels of the proposed standards, and similar to the PW4090 it is utilized on the Boeing 777-200 and 777-300. Due to the 1998 CAEP/4 NO_x standards, Pratt and Whitney has recently certified and manufactured these other or replacement engines. Also, based upon the CAEP/4 standards, they have already targeted future (after 2003) engine designs for modification so that newly certified or designed engines would meet today's proposed NO_x standards. Therefore, it appears unlikely that a substantial number of the 4 remaining engines would be built or sold in the future, unless they were produced as spare engines (replacement engines for existing aircraft instead of newly manufactured aircraft).

1. Effect of Market Forces

In 1998, FESG indicated at CAEP/4 that " * * * market forces and potential local/regional operating restrictions might encourage the manufacturers to modify their existing products, so that they, too, comply with the proposed stringency."¹⁰⁷ These modifications to in-production engines would be considered "voluntary environmental enhancement."¹⁰⁸ Thus, there was significant consideration at CAEP/4 given to the effect that new NO_x standards for newly certified engines would potentially have on in-production or already certified engines. Many parties within CAEP and its working groups consider market forces to have a real and tangible effect on newly manufactured or already certified engines, even though such engines are

not required to comply with the new standards. We are unaware of any new local/regional operating restrictions being implemented throughout the world due to the CAEP/4 NO_x standards. However, it seems some market forces from the CAEP/4 newly certified engine standards have affected production engines since there are now only four in-production engine models remaining from 1998 that would not meet the CAEP/4 standards. The Agency solicits comment on the effect market forces and potential local/regional operating restrictions might have on manufacturers to modify in-production or already certified engines.

2. Impact of Existing Fleet Aircraft

An element of the emissions proposals made at CAEP/4 was to increase NO_x stringency as far as possible without affecting the existing fleet aircraft asset values, and this was proposed to be achieved by applying the new stringency to new engine designs only (newly certified engines).¹⁰⁹ Two studies on whether the financial value of existing aircraft assets were affected by the CAEP/2 NO_x standards were reviewed for CAEP/4, and the studies did not reveal any correlation between approval of the CAEP/2 emissions standards and aircraft values. Thus, FESG was unable to definitively assess the effect CAEP/4 NO_x standards would have on fleet aircraft values.¹¹⁰ (The scope of the two studies and their ground rules were set by FESG.) These studies showed that a large number of factors impact aircraft asset values.

3. Request for Comment on Applying the Proposed NO_x standards to Already Certified Engines

As discussed earlier, FESG and CAEP working groups (specifically, Working Group 3—Emissions Technical Issues Working Group) are currently considering applying the 1998 CAEP/4 NO_x standards to engines built to already certified engine designs. Today, we are requesting comment on whether to apply the proposed NO_x standards, which are equivalent to the CAEP/4 NO_x standards, to already certified

engines.¹¹¹ Historically, EPA and ICAO have applied aircraft engine emission standards to already certified engines (or newly manufactured engines).¹¹² Although there is expected to be minimal environmental benefits (as well as relatively small costs) from such a requirement, it would ensure that manufacturers could not indefinitely produce existing engines that do not meet these standards (four such in-production or already certified engines models exist today).¹¹³

The implementation dates being analyzed by FESG and Working Group 3 for applying CAEP/4 standards to already certified engines are 2, 4, and 6 years after December 31, 2003 (the implementation date for newly certified engines). Based on the results of the complete assessment (which are not yet available), FESG and Working Group 3 are expected to recommend an implementation date for applying the CAEP/4 standards to already certified engines at CAEP/6 in February 2004 (a decision on this date is also expected at CAEP/6).¹¹⁴ If this requirement and date is accepted at CAEP/6, EPA would plan to propose the new requirement soon thereafter (see section IV.B. above for a discussion of the emission benefit of applying the proposed standards to already certified engines). We request comment on applying standards for already certified engines at a date 2, 4, and 6 years after the implementation date for new designs (2006, 2008, and 2010). Commenters suggesting different dates should specify the date(s) they prefer and, to the extent possible,

¹¹¹ Spare engines for existing aircraft would not be covered by such a requirement.

¹¹² EPA promulgated a HC standard in 1982 that applied to newly manufactured engines beginning in 1984. Also, the original ICAO NO_x, HC, and CO standards approved in 1981 applied to newly manufactured engines starting in 1986. In 1997, EPA adopted this CO standard, which was to be implemented later that same year for newly manufactured engines. In addition, the March 24, 1993 ICAO amendment to tighten the original NO_x standard by 20 percent (CAEP/2 standards), which EPA adopted in 1997, applied to newly certified engines beginning in 1996 and newly manufactured engines in 2000.

¹¹³ Nearly all engines built to already certified engine designs are likely to be in compliance with the proposed NO_x standards.

¹¹⁴ The FESG analysis mentioned earlier (CAEP-SG20022-WP/20, September 12, 2002) addresses the impact of applying the CAEP/4 NO_x standards to already certified engines at 2, 4, and 6 years after the implementation date of the CAEP/4 standards for newly certified engines. Yet, further assessment of the NO_x emission reductions was requested by the Steering Group for the next meeting in mid-2003. (ICAO, CAEP, Steering Group Meeting, Paris, France, September 10-13, 2002, "Summary of Discussions and Decisions of the First Meeting of the Steering Group," September 10, 2002, CAEP-SG20022-SD/1. See page 3. A copy of this paper can be found in Docket OAR-2002-0030.

¹⁰⁶ Although the remaining 4 engines (or two engine families) currently being built are expected to still be in production in year 2004, they would not be required to meet the proposed standards.

¹⁰⁷ ICAO, CAEP/4, Working Paper 4, "Economic Assessment of the EPG NO_x Stringency Proposal," March 12, 1998, Presented by the Chairman of FESG, Agenda Item 1: Review of proposals relating to NO_x emissions, including the amendment of Annex 16, Volume II, section 3.3.2 of the paper. A copy of this paper can be found in Docket OAR-2002-0030.

¹⁰⁸ However, FESG indicated that the " * * * the development of production engine emissions enhancements would only occur if the market place showed enough interest in the enhancements or if the failure to meet the proposed stringency became a competitive disadvantage." (ICAO, CAEP/4, Working Paper 4, "Economic Assessment of the EPG NO_x Stringency Proposal," March 12, 1998, Presented by the Chairman of FESG, Agenda Item 1: Review of proposals relating to NO_x emissions, including the amendment of Annex 16, Volume II, section 5.6.2 of the paper. A copy of this paper can be found in Docket OAR-2002-0030.

¹⁰⁹ ICAO, CAEP, Fourth Meeting, Montreal, Quebec, April 6-8, 1998, Report, Document 9720, CAEP/4. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

¹¹⁰ ICAO, CAEP/4, Working Paper 4, "Economic Assessment of the EPG NO_x Stringency Proposal," March 12, 1998, Presented by the Chairman of FESG, Agenda Item 1: Review of proposals relating to NO_x emissions, including the amendment of Annex 16, Volume II, section 4 of the paper. A copy of this paper can be found in Docket OAR-2002-0030.

provide technical and other justification for such suggested dates.

In addition, at this time the mobile sources (including aircraft engines) regulated under the authority of the Clean Air Act (Title II—Emission Standards for Moving Sources) have emission standards for newly manufactured engines or vehicles. However, except for aircraft engines, all current CAA mobile source programs involving new emission standards apply to newly manufactured engines or vehicles based on the certification model year (new standards apply to newly and already certified engines or vehicles in the same year). In these programs, EPA has incorporated emission averaging programs to make a more orderly product phase-in and phase-out (the average emissions within a manufacturer's product line is required to meet the applicable standard, which allows a manufacturer to produce some engine families with emission levels above the standard).¹¹⁵ However, averaging is not part of the ICAO protocol, and it is not clear that it is of any value here since most in-production engines already meet the proposed standards. Nonetheless, we solicit comment on whether an emission averaging program for such engines would be useful.

C. Amendments to Criteria on Calibration and Test Gases for Gaseous Emissions Test and Measurement Procedures

In today's proposed rule, EPA proposes to incorporate by reference ICAO's 1997 amendments to the criteria on calibration and test gases for the test procedures of gaseous emissions (ICAO International Standards and Recommended Practices Environmental Protection, Annex 16, Volume II, "Aircraft Engine Emissions," Second Edition, July 1993; Amendment 3, March 20, 1997, Appendices 3 and 5) in 40 CFR 87.64. ICAO's amendments, which became effective on March 20, 1997, apply to subsonic (newly certified and newly manufactured or already certified engines) and supersonic gas turbine engines. The proposed technical changes would correct a few inconsistencies between the specifications for carbon dioxide (CO₂) analyzers (Attachment B of Appendices 3 and 5) and the calibration and test gases (Attachment D of Appendices 3 and 5) of gaseous emissions. The test procedure amendments incorporated by

reference would be effective 60 days after the publication of the final rule.

For CAEP/3 in 1995, the Russian Federation presented a working paper entitled, "Corrections to Annex 16, Volume II," that stated the following:¹¹⁶

According to CAEP/2 recommendations, in the list of calibration and test gases (see the table in Attachment of Appendices 3 and 5) "CO₂ in N₂" was replaced with "CO₂ in air" gas. At the same time the following subparagraph was newly introduced into Attachment B (Appendices 3 and 5):

(g) The effect of oxygen (O₂) on the CO₂ analyzer response shall be checked. For a change from 0 percent O₂ to 21 percent O₂ the response of a given CO₂ concentration shall not change by more than 2 percent of reading. If this limit cannot be met and appropriate correction factor shall be applied.

Since the best way to carry out this checking procedure is to calibrate the analyzer first with CO₂ in nitrogen and then with CO₂ in air, both "CO₂ in N₂" and "CO₂ in air" gases have to be retained in the list. It seems then that "CO in air," "CO₂ in air," "NO in N₂" and now "CO₂ in N₂" have to be replaced with "CO in zero air," "CO₂ in zero air," "CO₂ in zero nitrogen" and "NO in zero nitrogen" just by analogy with the gaseous mixtures of different hydrocarbons diluted by zero air and listed in the same table.

In addition, at CAEP/3 the United Kingdom then presented a working paper on this same issue.¹¹⁷ They indicated that CAEP's Working Group 3 (Emissions Working Group) had accepted the above proposals of the Russian Federation paper on correcting inconsistencies in the list of calibration and test gases specified in Annex 16, Volume II, Attachment D to Appendices 3 and 5, and Working Group 3 had recommended that these proposals be presented at CAEP/3. The United Kingdom also recommended the adoption of these Russian Federation proposals—to utilize CO₂ in nitrogen gas mixture to check the effect of oxygen on CO₂ analyzers. In addition, they recommended the specification of all calibration and test gases required for all

the gaseous emissions tests required in Annex 16.

At CAEP/3, the CAEP members agreed that the above amendments to the calibration and test gases were justified, and thus, these amendments were then adopted.¹¹⁸ In today's notice, EPA proposes to incorporate by reference the amendments to the criteria on calibration and test gases for the test procedures of gaseous emissions, because the changes improve the test procedures by correcting inconsistencies and distinguishing between calibration and test gases. The amendments would include the following: (1) Listing all calibration gases separately from test gases for HC, CO₂, CO and NO_x analyzers, (2) changing "N₂" to "zero nitrogen" in relation to the test gases for the HC and NO_x analyzers, (3) adding "CO₂ in zero nitrogen" as a test gas for CO₂ analyzer, (4) changing "air" to "zero air" in relation to the test gas for CO and CO₂ analyzers, (5) revising the accuracy to "± 1 percent" for the "propane in zero air" test gas of HC analyzer, (6) amending the accuracy to "± 1 percent" for the "CO₂ in zero air" test gas of CO₂ analyzer, (7) adding the accuracy "± 1 percent" for the "CO₂ in zero nitrogen" test gas of CO₂ analyzer, (8) changing accuracy to "± 1 percent" for test gas of CO analyzer, and (9) revising accuracy to "± 1 percent" for test gas of NO_x analyzer.

Manufacturers are already voluntarily complying with ICAO's 1997 amendments to the criteria on calibration and test gases for the test procedures of gaseous emissions. Thus, formal adoption of these ICAO test procedure amendments would require no new action by manufacturers. In addition, the existence of ICAO's requirements would ensure that the costs of compliance (as well as the air quality impact) with these test procedures would be minimal. (In the 1982 and 1997 final rules on aircraft engine emissions (47 FR 58462, December 30, 1982 and 62 FR 25356, May 8, 1997, respectively), EPA incorporated by reference the then-existing ICAO testing and measurement procedures for aircraft engine emissions (ICAO International Standards and Recommended Practices Environmental Protection, Annex 16, Volume II, "Aircraft Engine Emissions," First and Second Editions, Appendices 3 and 5 were incorporated by reference in 40 CFR 87.64) in order to eliminate confusion over minor differences in

¹¹⁵ Typically, the calculations used for averaging are based upon an engine families yearly production or sales (among other characteristics—e.g., average power rating of engines families).

¹¹⁶ Russian Federation, "Corrections to Annex 16, Volume II," Agenda Item 2: Review of reports of working groups relating to engine emissions and the development of recommendations to the Council thereon, Working Paper 19, Presented by A.A. Gorbato, November 11, 1995 (distributed November 30, 1995), CAEP/3, Montreal, December 5 to 15, 1995. A copy of this paper can be found in Docket OAR-2002-0030.

¹¹⁷ United Kingdom, "Amendments to Annex 16, Volume II, Attachment D to Appendices 3 and 5 (Calibration and Test Gases)," Agenda Item 2: Review of reports of working groups relating to engine emissions and the development of recommendations to the Council thereon, Working Paper 20, Presented by M.E. Wright, November 14, 1995 (distributed November 30, 1995), CAEP/3, Montreal, December 5 to 15, 1995. A copy of this paper can be found in Docket OAR-2002-0030.

¹¹⁸ ICAO/CAEP, Report of Third Meeting, Montreal, Quebec, December 5–15, 1995, Document 9675, CAEP/3.

procedures for demonstrating compliance with the U.S. and ICAO standards.)

D. Correction of Exemptions for Very Low Production Models

Because of an editorial error, the section in the aircraft engine emission regulations regarding exemptions for very low production models is incorrectly specified (*see* section 40 CFR 87.7(b)(1) and (2)). In the October 18, 1984 final rulemaking (49 FR 41000), EPA intended to amend the low production engine provisions of the aircraft regulations by revising paragraph (b) and deleting paragraphs (b)(1) and (b)(2) in order to eliminate the maximum annual production limit of 20 engines per year. In the revisions to paragraph (b), EPA retained the maximum total production limit of 200 units for aircraft models certified after January 1, 1984.¹¹⁹ For § 87.7(b), EPA today proposes to correct this editorial error by eliminating paragraph (b)(1) and (b)(2).

As discussed further in the 1984 final rulemaking, this proposed action would provide more flexibility for engine manufacturers in scheduling during the last few engine production years. Also, the air quality impact of eliminating the annual production limit would be very small.

V. Coordination with FAA

The requirements contained in the notice are being proposed after consultation with the Secretary of Transportation in order to assure appropriate consideration of aircraft safety. Under section 232 of the CAA, the Secretary of Transportation (DOT) has the responsibility to enforce the aircraft emission standards established by EPA under section 231.¹²⁰ In addition, section 231(b) of the CAA states that "[a]ny regulation prescribed under this section * * * shall take effect (after consultation with the Secretary of Transportation) to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance * * *." As in past rulemakings and pursuant to the above referenced sections of the CAA, EPA has coordinated with the Federal Aviation Administration (FAA) of the DOT with respect to today's proposal.

Moreover, FAA is the official U.S. delegate to ICAO. FAA agreed to the

1997 and 1999 amendments at ICAO's Third and Fourth Meetings of the Committee on Aviation Environmental Protection (CAEP 3 and 4) after advisement from EPA.¹²¹ FAA and EPA are both members of the CAEP's Working Group 3 (among others), whose objective was to evaluate emissions technical issues and develop recommendations on such issues for CAEP 3 and 4. After assessing emissions test procedure amendments and new NO_x standards, Working Group 3 made recommendations to CAEP on these elements. These recommendations were then considered at the CAEP 3 and 4 meetings, respectively, prior to their adoption by ICAO in 1997 and 1999.

In addition, as discussed above, FAA would have the responsibility to enforce today's proposed requirements. As a part of its compliance responsibilities, FAA conducts the emission tests or delegates that responsibility to the engine manufacturer, which is then monitored by the FAA. Since the FAA does not have the resources or the funding to test engines themselves, FAA selects engineers at each plant to serve as representatives (called designated engineering representatives (DERs)) for the FAA while the manufacturer performs the test procedures. DERs' responsibilities include evaluating the test plan, the test engine, the test equipment, and the final testing report sent to FAA. DERs' responsibilities are determined by the FAA and today's proposal would not affect their duties.

VI. Possible Future Aviation Emission Reductions (EPA/FAA Voluntary Aviation Emissions Reduction Initiative)

There is growing interest, particularly at the state and local level, in addressing emissions from aircraft and other aviation-related sources. Such interest is often related to plans for airport expansion which is occurring across the country. It is possible that other approaches may provide effective avenues to achieve additional aviation emission reductions, beyond EPA establishing aircraft engine emission standards. The Agency invites comment on the potential approach for additional reductions discussed below and any other approaches.

Concerns by state and local air agencies and environmental and public health organizations about aviation emissions, led to EPA and FAA signing a memorandum of understanding

(MOU) in March 1998 agreeing to work to identify efforts that could reduce aviation emissions.¹²² Since that time FAA and EPA have jointly chaired a national stakeholder initiative whose goal is to develop a voluntary program to reduce pollutants from aircraft and other aviation sources that contribute to local and regional air pollution in the United States. The major stakeholders participating in this initiative include representatives of the aviation industry (passenger and cargo airlines and engine manufacturers), airports, state and local air pollution control officials, environmental organizations, and NASA.

Initially, the discussions with stakeholders focused on the prospect of aircraft engine emission reduction retrofit kits, which might be applied to certain existing aircraft engines.¹²³ However, as the initiative evolved, the focus was expanded by the stakeholders to identify strategies for various types of ground service equipment (GSE) in use at airports (*e.g.*, baggage tugs and fuel trucks),¹²⁴ in addition to strategies to reduce aircraft emissions.¹²⁵ Due to the differences in time and technology that it takes to reduce aircraft emissions versus that for GSE, the stakeholders are seeking to reach a consensus on a distinctly two-step program to voluntarily achieve wide-scale emissions reductions from GSE and aircraft. Near term efforts will focus on emissions reductions from GSE, and long term efforts will focus on reductions from aircraft.¹²⁶

The stakeholders are currently discussing a framework for reaching

¹²² FAA and EPA, "Agreement Between Federal Aviation Administration and Environmental Protection Agency Regarding Environmental Matters Relating to Aviation," signed on March 24, 1998 by FAA's Acting Assistant Administrator for Policy, Planning, and International Aviation, Louise Maillet, and EPA's Acting Assistant Administrator for Air and Radiation, Richard Wilson. A copy of this document can be found in Docket OAR-2002-0030.

¹²³ Two engine models were indeed certificated with emissions retrofit kits, and a number of these engines have been purchased for aircraft with the retrofit kits installed in their stock configuration. However, retrofit kits have not to date provided widescale emissions improvements because it seems they may have limited applicability to certain engine types, small emission benefits, and cost issues.

¹²⁴ The stakeholders are now considering the impact, operation and design of GSE at airports, with projects being undertaken at several airports to reduce overall emissions.

¹²⁵ Operational strategies, such as reducing the time in which aircraft are in idle and taxi modes and the impact of auxiliary power units (APUs) have also been considered.

¹²⁶ The stakeholder program for aircraft emissions reductions is viewed as a supplement to the traditional regulatory approach of establishing engine emission standards.

¹¹⁹ This action was taken in 1984 to provide greater flexibility to manufacturers for scheduling engine production rates during the final years.

¹²⁰ Specifically, the FAA of the DOT has the responsibility to enforce the aircraft emission standards established by EPA.

¹²¹ The Third Meeting of CAEP (CAEP/3) occurred in Montreal, Quebec from December 5 through 15 in 1995. CAEP/4 took place in Montreal from April 6 through 8, 1998.

consensus on the goals or targets for emissions reductions, timing, accountability, State Implementation Plan implications (including general conformity), and numerous other issues that have been raised for GSE and aircraft emission reductions. If this initiative is successful, an agreement would be reached among all the stakeholders on a national voluntary aviation emissions reduction program. The mechanism that could be used to codify or enforce an eventual agreement has yet to be determined. The overall goal of the EPA/FAA voluntary initiative is to develop a program that will achieve significant national emission reductions.

VII. Regulatory Impacts

Aircraft engines are international commodities, and thus, they are designed to meet international standards. Today's proposal would have the benefit of establishing consistency between U.S. and international emission standards and test procedures. Thus, an emission certification test which meets U.S. requirements would also be applicable to all ICAO requirements. Engine manufacturers are already developing improved technology in response to the ICAO standards that match the standards proposed here, and EPA does not believe that the costs incurred by the aircraft industry as a result of the existing ICAO standards should be attributed to today's proposed regulations (as discussed above, these standards only apply to newly certified or designed engines, but not already certified, newly manufactured or in-production engines). Also, the test procedure amendments (revisions to criteria on calibration and test gases) necessary to determine compliance are already being adhered to by manufacturers during current engine certification tests. Therefore, EPA believes that the proposed regulations would impose no additional burden on manufacturers.

The existence of ICAO's requirements results in minimal cost as well as air quality benefits from today's proposed requirements.¹²⁷ Since aircraft and aircraft engines are international commodities, there is significant

commercial benefit to consistency between U.S. and international emission standards and control program requirements. Also, EPA's proposed adoption of the ICAO standards and related test procedures would be consistent with our treaty obligations and strengthen the U.S. position in future ICAO/CAEP processes related to emission standards.

VIII. Public Participation

We request comment on all aspects of this proposal. This section describes how you can participate in this process.

A. How Do I Submit Comments?

We are opening a formal comment period by publishing this document. We will accept comments during the period indicated under **DATES** above. If you have an interest in the proposed emission control program described in this document, we encourage you to comment on any aspect of this rulemaking. We also request comment on specific topics identified throughout this proposal.

Your comments will be most useful if you include appropriate and detailed supporting rationale, data, and analysis. Commenters are especially encouraged to provide specific suggestions for any changes to any aspect of the regulations that they believe need to be modified or improved. You should send all comments, except those containing proprietary information, to our Air Docket (see section I.C under **SUPPLEMENTARY INFORMATION** before the end of the comment period.

If you submit proprietary information for our consideration, you should clearly separate it from other comments by labeling it "Confidential Business Information." You should also send it directly to the contact person listed under **FOR FURTHER INFORMATION CONTACT** instead of to the public docket. This will help ensure that no one inadvertently places proprietary information in the docket. If you want us to use your confidential information as part of the basis for the final rule, you should send a nonconfidential version of the document summarizing the key data or information. We will disclose information covered by a claim of confidentiality only through the application of procedures described in 40 CFR part 2. If you don't identify information as confidential when we receive it, we may make it available to the public without notifying you.

B. Will There Be a Public Hearing?

We will hold a public hearing on November 13, 2003 at the Environmental Protection Agency, EPA

East Building, Room Number 1153, 1201 Constitution Avenue, NW., Washington, DC 20004, Telephone: (202) 564-1682. The hearing will start at 10 a.m. local time and continue until everyone has had a chance to speak.

If you would like to present testimony at the public hearing, we ask that you notify the contact person listed under **FOR FURTHER INFORMATION CONTACT** at least ten days before the hearing. You should estimate the time you will need for your presentation and identify any needed audio/visual equipment. We suggest that you bring copies of your statement or other material for the EPA panel and the audience. It would also be helpful if you send us a copy of your statement or other materials before the hearing.

We will make a tentative schedule for the order of testimony based on the notifications we receive. This schedule will be available on the morning of the hearing. In addition, we will reserve a block of time for anyone else in the audience who wants to give testimony.

We will conduct the hearing informally, and technical rules of evidence won't apply. We will arrange for a written transcript of the hearing and keep the official record of the hearing open for 30 days to allow you to submit supplementary information. You may make arrangements for copies of the transcript directly with the court reporter.

IX. Statutory Authority

The statutory authority for today's proposal is provided by sections 231 and 301(a) of the Clean Air Act, as amended, 42 U.S.C. 7571 and 7601. See section III of today's NPRM for discussion of how EPA meets the CAA's statutory requirements.

X. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

¹²⁷ CAEP's Forecasting and Economic Analysis Support Group (FESG) concluded at CAEP/4 that their assessment of these new NO_x standards indicates that the direct costs of the standards would be minimal, and the benefits would be modest. (ICAO, CAEP/4, Working Paper 4, "Economic Assessment of the EPG NO_x Stringency Proposal," March 12, 1998, Presented by the Chairman of FESG, Agenda Item 1: Review of proposals relating to NO_x emissions, including the amendment of Annex 16, Volume II. A copy of this paper can be found in Docket OAR-2002-0030.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

EPA has determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review. Today's action would codify emission standards that manufacturers currently adhere to (nearly all in-production engines already meet the standards). The proposed standards are equivalent to the ICAO international consensus standards. These proposed standards would not impose any additional burden on manufacturers because they are already designing new engines to meet the ICAO standards. Thus, the annual effect on the economy of today's proposed standards would be minimal, and none of the other thresholds identified in the executive order would be triggered by this action.

B. Paperwork Reduction Act

This action does not impose any information collection burden under provisions of the Paperwork Reduction

Act, 44 U.S.C. 3501 *et seq.* Any reporting and recordkeeping requirements associated with these standards would be defined by the Secretary of Transportation in enforcement regulations issued later under the provisions of section 232 of the Clean Air Act. Since most if not all manufacturers already measure NO_x and report the results to the FAA, any additional reporting and record keeping requirements associated with FAA enforcement of these proposed regulations would likely be very small.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to

respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that meet the definition for business based on SBA size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The following table 1 provides an overview of the primary SBA small business categories potentially affected by this proposed regulation.

TABLE X.C-1—PRIMARY SBA SMALL BUSINESS CATEGORIES POTENTIALLY AFFECTED BY THIS PROPOSED REGULATION

| Industry | NAICS ^a codes | Defined by SBA as a small business if: ^b |
|---|--------------------------|---|
| Manufacturers of new aircraft engines | 336412 | <1,000 employees |
| Manufacturers of new aircraft | 336411 | <1,500 employees |
| Scheduled air carriers, passenger and freight | 481 | <1,500 employees |

^a North American Industry Classification System (NAICS)

^b According to SBA's regulations (13 CFR part 121), businesses with no more than the listed number of employees or dollars in annual receipts are considered "small entities" for purposes of a regulatory flexibility analysis.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Because of the limited classes of aircraft engines to which today's proposed regulations apply, no small entities would be affected. Our review of the list of manufacturers of commercial aircraft gas turbine engines with rated thrust greater than 26.7 kN indicates that there are no U.S. manufacturers of these engines that qualify as small businesses. We are unaware of any foreign manufacturers with a U.S.-based facility that would qualify as a small business. In addition,

the proposed rule will not impose significant economic impacts on engine manufacturers. As discussed earlier, today's action would codify emission standards that manufacturers currently adhere to (nearly all in-production engines already meet the standards). The proposed standards are equivalent to the ICAO international consensus standards. These proposed standards would not impose any additional burden on manufacturers because they are already designing new engines to meet the ICAO standards. Also, the test procedure amendments (revisions to criteria on calibration and test gases) necessary to determine compliance are already being adhered to by manufacturers during current engine certification tests. Therefore, EPA

believes that the proposed regulations would impose no additional burden on manufacturers. The existence of ICAO's requirements results in minimal cost from today's proposed requirements. We invite comments on all aspects of the proposal and its impacts on small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules

with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditure of \$100 million or more for State, local, or tribal governments, in the aggregate or the private sector in any one year. This rule contains no regulatory requirements that might significantly or uniquely affect small governments. Today's action would codify emission standards that manufacturers currently adhere to (nearly all in-production engines already meet the standards). The proposed standards are equivalent to the ICAO international consensus standards. These proposed standards would not impose any additional burden on manufacturers because they are already designing new engines to meet the ICAO standards. Thus, the annual effect on the economy of today's proposed standards will be minimal. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure

"meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. As discussed earlier, section 233 of the CAA preempts states from adopting or enforcing aircraft engine emission standards. This proposed rule merely modifies existing EPA aircraft engine emission standards and test procedures and therefore will merely continue an existing preemption of State and local law. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications."

This proposed rule does not have tribal implications as specified in Executive Order 13175. The proposed emission standards and other related requirements for private industry in this rule have national applicability and therefore do not uniquely affect the communities of Indian Tribal Governments. As discussed earlier, section 233 of the CAA preempts states from adopting or enforcing aircraft engine emission standards. This proposed rule merely modifies existing EPA aircraft engine emission standards and test procedures and therefore will merely continue an existing preemption of State and local law. In addition, this rule will be implemented at the Federal level and impose compliance

obligations only on engine manufacturers. Thus, Executive Order 13175 does not apply to this rule. EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, Section 5-501 of the Order directs the Agency to evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposal is not subject to Executive Order 13045 because it is not economically significant under the terms of Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

The effects of ozone and PM on children's health were addressed in detail in EPA's rulemaking to establish NAAQS for these pollutants, and EPA is not revisiting those issues here. EPA believes, however, that the emission reductions (NO_x and secondary PM) from this rulemaking will further reduce ozone and PM and the related adverse impacts on children's health.

The public is invited to submit or identify peer-reviewed studies and data, of which the agency may not be aware, that assessed results of early life exposure to ozone and PM.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement

Act of 1995 ("NTTAA"), Public Law 104-113, section 12(d) (15 U.S.C. 272 *note*) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking involves technical standards for testing emissions for commercial aircraft gas turbine engines. EPA proposes to use test procedures contained in ICAO International Standards and Recommended Practices Environmental Protection, with the proposed modifications contained in this rulemaking.¹²⁸ These procedures are currently used by all manufacturers of commercial aircraft gas turbine engines (with thrust greater than 26.7 kN) to demonstrate compliance with ICAO emissions standards.

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

List of Subjects in 40 CFR Part 87

Environmental protection, Air pollution control, Aircraft, Incorporation by reference.

Dated: September 12, 2003.

Marianne Lamont Horinko,
Acting Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 87—CONTROL OF AIR POLLUTION FROM AIRCRAFT AND AIRCRAFT ENGINES

1. The authority citation for part 87 continues to read as follows:

Authority: Secs. 231, 301(a), Clean Air Act, as amended (42 U.S.C 7571, 7601(a)).

¹²⁸ ICAO International Standards and Recommended Practices Environmental Protection, Annex 16, Volume II, "Aircraft Engine Emissions," Second Edition, July 1993—Amendment 3, March 20, 1997. Copies of this document can be obtained from ICAO (<http://www.icao.int>).

Subpart A—[Amended]

2. Section 87.7 is amended by removing paragraphs (b)(1) and (b)(2).

Subpart C—[Amended]

3. Section 87.21 is amended by adding paragraph (d)(1)(vi) to read as follows:

§ 87.21 Standards for exhaust emissions.

* * * * *

(d) * * *

(1) * * *

(vi) Engines of a type or model of which the date of manufacture of the first individual production model was after December 31, 2003:

(A) Engines with a rated pressure ratio of 30 or less:

(1) Engines with a maximum rated output greater than 89 kilonewtons: Oxides of Nitrogen: $(19 + 1.6(\text{rPR}))$ grams/kilonewtons rO.

(2) Engines with a maximum rated output greater than 26.7 kilonewtons but not greater than 89 kilonewtons: Oxides of Nitrogen: $(37.572 + 1.6(\text{rPR}) - 0.2087(\text{rO}))$ grams/kilonewtons rO.

(B) Engines with a rated pressure ratio greater than 30 but less than 62.5:

(1) Engines with a maximum rated output greater than 89 kilonewtons: Oxides of Nitrogen: $(7 + 2(\text{rPR}))$ grams/kilonewtons rO.

(2) Engines with a maximum rated output greater than 26.7 kilonewtons but not greater than 89 kilonewtons: Oxides of Nitrogen: $(42.71 + 1.4286(\text{rPR}) - 0.4013(\text{rO}) + 0.00642(\text{rPR} - \text{rO}))$ grams/kilonewtons rO.

(C) Engines with a rated pressure ratio of 62.5 or more:

Oxides of Nitrogen: $(32 + 1.6(\text{rPR}))$ grams/kilonewtons rO.

* * * * *

Subpart G—[Amended]

4. Section 87.64 is revised to read as follows:

§ 87.64 Sampling and analytical procedures for measuring gaseous exhaust emissions.

The system and procedures for sampling and measurement of gaseous emissions shall be as specified by Appendices 3 and 5 to International Civil Aviation Organization (ICAO) Annex 16, Environmental Protection, Volume II, Aircraft Engine Emissions, Second Edition, July 1993 (including Amendment 3 of March 20, 1997), which are incorporated herein by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they

exist on the date of the approval and a notice of any change in these materials will be published in the **FEDERAL REGISTER**. Frequent changes are not anticipated. Copies may be inspected at U.S. EPA, Air and Radiation Docket and Information Center, 1301 Constitution Ave., NW., Room B102, EPA West Building, Washington, DC 20460, or at the Office of the **Federal Register**, 800 North Capitol Street, NW., 7th Floor, Suite 700, Washington DC. Copies of this document can be obtained from the International Civil Aviation Organization (ICAO), Document Sales Unit, 999 University Street, Montreal, Quebec, Canada H3C 5H7.

5. Section 87.71 is revised to read as follows:

§ 87.71 Compliance with gaseous emission standards.

Compliance with each gaseous emission standard by an aircraft engine shall be determined by comparing the pollutant level in grams/kilonewton/thrust/cycle or grams/kilowatt/cycle as calculated in § 87.64 with the applicable emission standard under this part. An acceptable alternative to testing every engine is described in Appendix 6 to International Civil Aviation Organization (ICAO) Annex 16, Environmental Protection, Volume II, Aircraft Engine Emissions, Second Edition, July 1993 (including Amendment 3 of March 20, 1997), which is incorporated herein by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the **FEDERAL REGISTER**. Frequent changes are not anticipated. Copies may be inspected at U.S. EPA, Air and Radiation Docket and Information Center, 1301 Constitution Ave., NW., Room B102, EPA West Building, Washington, DC 20460, or at the Office of Federal Register, 800 North Capitol Street, NW., 7th Floor, Suite 700, Washington DC. Copies of this document can be obtained from the International Civil Aviation Organization (ICAO), Document Sales Unit, 999 University Street, Montreal, Quebec, Canada H3C 5H7. Other methods of demonstrating compliance may be approved by the Secretary with the concurrence of the Administrator.

6. Section 87.82 is revised to read as follows:

§ 87.82 Sampling and analytical procedures for measuring smoke exhaust emissions.

The system and procedures for sampling and measurement of smoke emissions shall be as specified by Appendix 2 to International Civil Aviation Organization (ICAO) Annex 16, Volume II, Environmental Protection, Aircraft Engine Emissions, Second Edition, July 1993 (including Amendment 3 of March 20, 1997), which are incorporated herein by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the **Federal Register**. Frequent changes are not anticipated. Copies may be inspected at U.S. EPA, Air and Radiation Docket and Information Center, 1301 Constitution Ave., NW., Room B102, EPA West Building, Washington, DC 20460, or at the Office of the Federal Register, 800 North Capitol Street, NW., 7th Floor, Suite 700, Washington DC. Copies of this document can be obtained from the International Civil Aviation Organization (ICAO), Document Sales Unit, 999 University Street, Montreal, Quebec, Canada H3C 5H7.

7. Section 87.89 is revised to read as follows:

§ 87.89 Compliance with smoke emission standards.

Compliance with each smoke emission standard shall be determined by comparing the plot of SN as a function of power setting with the applicable emission standard under this part. The SN at every power setting must be such that there is a high degree of confidence that the standard will not be exceeded by any engine of the model being tested. An acceptable alternative to testing every engine is described in Appendix 6 to International Civil Aviation Organization (ICAO) Annex 16, Environmental Protection, Volume II, Aircraft Engine Emissions, Second Edition, July 1993 (including Amendment 3 of March 20, 1997), which is incorporated herein by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the **Federal Register**. Frequent changes are not anticipated. Copies may be inspected at U.S. EPA, Air and Radiation Docket and

Information Center, 1301 Constitution Ave., NW., Room B102, EPA West Building, Washington, DC 20460, or at the Office of the Federal Register, 800 North Capitol Street, NW., 7th Floor, Suite 700, Washington DC. Copies of this document can be obtained from the International Civil Aviation Organization (ICAO), Document Sales Unit, 999 University Street, Montreal, Quebec, Canada H3C 5H7.

[FR Doc. 03-24412 Filed 9-29-03; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AI68

Endangered and Threatened Wildlife and Plants; Listing of the Central California Distinct Population Segment of the California Tiger Salamander; Reclassification of the Sonoma County and Santa Barbara County Distinct Populations from Endangered to Threatened; Special Rule

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the reopening of the comment period for the proposed rule that would: List the Central California distinct population segment (DPS) of the California tiger salamander (*Ambystoma californiense*) as a threatened species under the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*); reclassify the Sonoma County and Santa Barbara County DPSs of the California tiger salamander from endangered to threatened; and exempt, under section 4(d) of the Act, existing routine ranching activities on private or Tribal lands from section 9 prohibitions for the Central California DPS of the California tiger salamander and, if reclassified to threatened, for the Santa Barbara and Sonoma County DPSs. Comments previously submitted need not be resubmitted, as they will be incorporated into the public record as part of this reopened comment period and will be fully considered in the final rule.

DATES: Comments and information from all interested parties will be accepted until 5 p.m. on October 31, 2003.

ADDRESSES: (1) You may submit written comments to the Field Supervisor (Attn:

CTS), U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Suite W-2605, Sacramento, CA 95825.

(2) You may send comments by electronic mail (e-mail) to: catiger@R1.fws.gov. See the "Public Comments Solicited" section below for file format and other information on electronic filing.

(3) You may hand-deliver comments to our Sacramento Fish and Wildlife Office at the address above.

Comments and materials received, as well as supporting documentation used in the preparation of the proposed rule, will be available for public inspection, by appointment, during normal business hours, at the above address. You may obtain copies of the proposed rule from the above address, by calling 916/414-6600, or from our Web site at <http://sacramento.fws.gov>.

FOR FURTHER INFORMATION CONTACT:

Adam Zerrenner or Arnold Roessler of the Sacramento Fish and Wildlife Office, 2800 Cottage Way Room W-2605, Sacramento, CA 95825 (telephone 916/414-6600, facsimile 916/414-6713, or visit our Web site at <http://sacramento.fws.gov/>). Information regarding this proposal is available in alternative formats upon request.

SUPPLEMENTARY INFORMATION:

Background

On May 23, 2003, we published a proposed rule to list the Central California DPS of the California tiger salamander as a threatened species (68 FR 28647). The rule also proposed to reclassify the Sonoma County and Santa Barbara County DPSs from endangered to threatened. In addition, the proposed rule included a special rule to exempt, under section 4(d) of the Act, existing routine ranching activities from ?take? prohibitions under section 9 of the Act for the Central California DPS of the California tiger salamander and, if reclassified to threatened, for the Santa Barbara and Sonoma County DPSs. On July 3, 2003, we published a document to extend the comment period for the proposed rule to September 22, 2003 (68 FR 39892). For further information regarding background biological information, previous Federal actions, factors affecting the species, and conservation measures available to these three DPSs of the California tiger salamander, please refer to the proposed rule (68 FR 28647; May 23, 2003).

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible.



Division of Enforcement

Memorandum

TO: David K. Paylor, Director

FROM: Michael G. Dowd, Director, Division of Enforcement

DATE: June 26, 2007

Cc: James J. Golden, Deputy Director of Operations

SUBJECT: Analysis of Why Proposed Stack Merge Project for Mirant's Potomac River Generating Station Does Not Require Minor New Source Review Permit

Introduction

Mirant has proposed to merge the five existing smokestacks at the Potomac River Generating Station (the plant) into two stacks; the smaller units 1 and 2 are proposed to vent through the first stack and the larger units 3, 4, and 5 are proposed to vent through the second stack. According to Mirant, the stack merge project entails principally the installation of new induced draft (ID) fans and exhaust ducting. The new ID fans would be larger than the existing ID fans in order to overcome the increased resistance of the longer, more jointed exhaust ducts according to Mirant. In September 2006, DEQ initially and tentatively concluded that the stack merge project would be subject to minor new source review (NSR) permit requirements under 9 VAC 5 Chapter 80, Article 6. This tentative conclusion was based on the fact that at that time Mirant had provided DEQ with little technical information regarding the potential of the project, in particular the new ID fans, to increase the capacity of the plant's boilers and hence the plant's emissions. Without such information, it was impossible for DEQ to conclude that the project would not result in a net emissions increase.

Since that time, Mirant has submitted a revised Form 7 permit application dated April 9, 2007, as well as supplied DEQ with additional engineering and technical information in correspondence dated February 9, 2007, May 31, 2007, June 4, 2007, and June 11, 2007, in support of the stack merge project. Based on review of that additional information provided by Mirant and as discussed below, DEQ now can reasonably conclude that construction of the stack merge project, along with the installation and operation of its related equipment, is exempt from the minor new source permitting requirements of 9 VAC 5 Chapter 80, Articles 6.

Discussion

Minor NSR permit applicability is premised on “a physical change in, or change in the method of operation, or addition to, a stationary source that would result in a net emission increase of any regulated air pollutant...” 9 VAC 5 Chapter 80, Article 6. Obviously, the stack merge project entails a physical change to a stationary source, i.e., the plant.

The next step in the analysis is to examine whether the project “would result in a net emissions increase.” “Net emission increase” is defined in Article 6 as:

“the amount by which the sum of the following exceeds zero: (i) any increase in *actual emissions* from a particular physical change or change in the method of operation at a stationary source and (ii) any other increases and decreases in actual emissions at the source that are concurrent with the particular change and are otherwise creditable. An increase or decrease in actual emissions is concurrent with the increase from the particular change only if it is directly resultant from the particular change. An increase or decrease in actual emissions is not creditable if the board has relied on it in issuing a permit for the source under the new source review program and that permit is in effect when the increase in actual emissions from the particular change occurs. Creditable increases and decreases shall be federally enforceable or enforceable as a practical matter.”

9 VAC 5-80-1110.C. (Emphasis added). In order for the minor NSR permit requirements to apply, therefore, the physical change must *result* in an increase in “actual emissions,” which simply rephrases the awkward regulatory language that says the increase in “actual emissions” must “be from” the physical change.

An argument can be made that the permit analysis for the stack merge project ends at this point because Mirant has submitted engineering data that details the lack of effect the larger ID fans would have on the balanced draft operations of the plant’s boilers. In addition, Mirant provided certification from a Professional Engineer claiming that the project would not increase the plant’s capacity or emissions. (See letter from Richard Storm, P.E., to David Cramer dated June 11, 2007.) Assuming the engineering analysis submitted by Mirant and the certification by the Professional Engineer are correct, and thus far DEQ has come across no indication to the contrary, the project could not physically result in an emissions increase.

One might argue that even though the stack merge project does not physically enable the plant to increase its emissions, the project nevertheless should be subject to permitting because the plant may increase its hours of operation upon completion of the project, thus increasing its emissions from the time immediately prior to the project. It is important to note here that the regulations make clear that an increase in the production

rate or the hours of operation of a unit do not by themselves constitute a "modification" subjecting the unit to a permit. However, if the increase in the hours of operation is related in some manner to a physical change then the resulting emission increases may be considered to be "from" that physical change.

In this case, it may be argued that any increases in emissions that take place between the time immediately prior to the project and the time following completion of the project are related to the stack merge in so far as the project could allow increased operation while still maintaining the plant's compliance with the NAAQS. Therefore, it is prudent to take the permit analysis here to the next step and examine in greater depth the meaning of "actual emissions" under Article 6.

"Actual emissions" are defined in Article 6 to mean:

"the actual rate of emissions (expressed in tons per year) of a pollutant from a stationary source or portion thereof, as determined in accordance with the provisions of this definition.

1. In general, actual emissions as of a particular date shall equal the average rate, in tons per year, at which the unit actually emitted the pollutant during a two-year period that precedes the particular date and that is representative of normal source operation. The board will allow the use of a different time period upon a determination that it is more representative of normal source operation. Actual emissions shall be calculated using the unit's actual operating hours, production rates, and types of materials processed, stored, or combusted during the selected time period.

2. The board may presume that source-specific allowable emissions for the emissions unit are equivalent to the actual emissions of the unit.

3. For any emissions unit which has not begun normal operations on the particular date, actual emissions shall equal the potential to emit of the unit on that date."

9 VAC 5-80-1110.C. Under this definition of "actual emissions," minor NSR permit applicability for units that have "begun normal operations" prior to the modification is based on a comparison of the unit's pre-change actual emissions with a projection of the unit's post-change actual emissions resulting from the change. On the other hand, permit applicability for units that have not "begun normal operations" as of the date of the modification is based on a comparison of the unit's pre-change actual emissions with its post-change potential emissions.

The term "begun normal operations" is not defined in the regulations so its interpretation is left to the informed judgment of DEQ. In this case, based on the information provided by Mirant and the Professional Engineer, as well as upon a

commonsense understanding of the term, it is reasonable for DEQ to conclude that the stack merge project would not affect the plant's units to such an extent that they could not be considered to have begun normal operation prior to completion of the project. All five of the plant's boiler units have been in operation since the early 1950s. The stack merge project does not modify the boiler houses but only the ID fans, which are located downstream of the electrostatic precipitators (ESPs), and the exhaust ducting. Moreover, as explained by the Professional Engineer, the project will not increase the capacity of the boiler units or affect their balanced draft operations. The Professional Engineer states in his letter:

"The fuel burning system capacity is primarily governed by the capacity of the pulverizers and forced draft fans. The FD fans are the fans that provide combustion air airflow to the furnace.... The...[ID] fans simply remove the combustion products from the furnace and draw them through the convection pass of the boiler, air heaters, ductwork and electrostatic precipitators, then discharging the flow of flue gases to the stack. The total heat input to the furnace is regulated by varying the FD fan flow rates and the coal feed rates to each of the pulverizers."

According to the Professional Engineer, the stack merge project requires larger ID fans in order simply to maintain the current balanced draft through the furnace due to the longer and more jointed exhaust ductwork that the merged stacks require. The operation of the boiler units themselves, however, will remain unchanged following completion of the stack merge project. Since the operation of the boiler units will remain unchanged following the stack merge, DEQ can reasonably conclude that the plant's emission units will have already begun normal operation before completion of the project.

Thus, because DEQ believes the plant's emission units will have already begun normal operations prior to the stack merge project, the proper way to analyze whether a minor NSR permit is required for the project is to compare the plant's emission units' pre-change actual emissions with a projection of the units' post-change actual emissions resulting from the changes brought on by the project.

Generally, an emission unit's pre-change actual emissions are calculated using the two-year period, i.e., "baseline," that immediately precedes the date of the change. However, if the two-year period immediately preceding the change is not representative of normal operations of the source, the regulations allow for the use of a different two-year time period that is more representative of normal operation. After careful consideration, DEQ selected 2002-2003 as the baseline period most representative of the plant's normal operations. (See DEQ's DRAFT Permit and Engineering Analysis for the Potomac River Generating Station, March 16, 2007, pages 6-7, for a detailed discussion of the selection of 2002-2003 baseline period for the stack merge project.)

Upon comparing the plant's actual emissions during the 2002-2003 baseline period with a projection of the plant's post-change actual emissions resulting from the stack merge project, DEQ can conclude that the project would not result in a net

emissions increase for the following three reasons: First, the recent engineering and technical information supplied by Mirant concerning the project, and in particular the information certified by the Professional Engineer discussed above, indicate the project can not physically result in an increase in emissions. Second, the annual 3700 ton NO_x limit imposed on the plant for 2007 and beyond pursuant to the Mirant NO_x Consent Decree entered in federal court on April 20, 2007, will limit the plant's emissions of NO_x, as well as by necessity other pollutants of concern, to levels below those emitted by the plant during the 2002-2003 baseline period. (See letter to Jim Sydnor from Dave Cramer dated June 6, 2007.) Third, the comprehensive permit that the board likely will issue this year before completion of the stack merge project will, with near certainty, restrict the plant's emissions of SO₂, as well as other pollutants, to levels well below of the 2002-2003 baseline.

Conclusion

Based on the above analysis, DEQ now can reasonably conclude that the stack merge project will not result in a net emissions increase at the plant and, therefore, the project is exempt from minor NSR permit requirements under 9 VAC 5 Chapter 80, Article 6.

From: Paylor,David <dkpaylor@deq.virginia.gov>
Sent: Wednesday, June 6, 2007 3:43 PM
To: Dowd,Michael <mgdowd@deq.com>
Subject: FW: NSR Appliability re: Mirant
Attach: Mirant Past NSR Applicability Determination Review.doc; VOC Emissions After Control Equipment.doc; JD CO Policy Memo.pdf; Mirant Major NSR Timeline.xls

-----Original Message-----

From: Katz,Judith@epamail.epa.gov [<mailto:Katz.Judith@epamail.epa.gov>]

Sent: Friday, April 27, 2007 11:31 AM

To: Sydnor,James

Cc: Paylor,David; Steers,Jeffery; Golden,James; Dowd,Michael; Weeks,Richard; Thompson,Tamera; Campbell.Dave@epamail.epa.gov

Subject: Re: NSR Appliability re: Mirant

Thanks, Jim. We will do our best to meet your deadline of May 15. We are also working on an answer to your question about credit for merging the stacks, and hope to have that answer by then as well. Judy

"Sydnor,James"

<jesydnor@deq.virginia.gov>

To

Judith Katz/R3/USEPA/US@EPA

04/27/2007 10:09 AM

cc

"Thompson,Tamera"

<tmthompson@deq.virginia.gov>,

"Golden,James"

<jjgolden@deq.virginia.gov>,

"Weeks,Richard"

<rfweeks@deq.virginia.gov>,

"Paylor,David"

<dkpaylor@deq.virginia.gov>,

"Steers,Jeffery"

<jasteers@deq.virginia.gov>,

"Dowd,Michael"

<mgdowd@deq.virginia.gov>

Subject

NSR Appliability re: Mirant

Judy,

Attached is the information regarding our NSR applicability determination for the Mirant Potomac River Generating Station. As we

DEQ-1B-02574

discussed, we are requesting your review of this documentation and EPA's opinion regarding our conclusions that NSR was not triggered at this facility as a result of the installation of LNBS, SOFA, and the Trona system. Your reply by May 15th is requested. Please let us know if you have questions or wish to discuss this further.

James E. Sydnor
Va. Dept. of Env. Quality
Director, Air Division
804-698-4424

(See attached file: Mirant Past NSR Applicability Determination Review.doc)(See attached file: VOC Emissions After Control Equipment.doc)(See attached file: JD CO Policy Memo.pdf)(See attached file: Mirant Major NSR Timeline.xls)

Summary of Past NSR Applicability Determination Review for the Mirant Potomac River Generating Station

The Department of Environmental Quality staff conducted a review of all past actions conducted by the Mirant Potomac River Generating Station (PRGS) in Alexandria, Virginia to determine whether New Source Review (NSR) should have applied. Staff evaluated over 75 different projects that have taken place in the past several years with a focus on three specific projects. The projects were the installation of Low NO_x Burners (LNB), Separated Over-Fired Air (SOFA) and Trona. After review by DEQ staff, it has been determined that NSR applicability was not triggered as a result of these actions at PRGS.

Installation of Low NO_x Burners

As a result of the federal Consent Decree, LNBs were installed at PRGS in April 2004 for units 3, 4, & 5 and September 2004 for units 1 & 2. At the time of installation, EPA's NSR reform regulations (promulgated 12/31/2002) had a provision for Pollution Control Projects (PCP) which allows for an increase of one pollutant if the decrease in another pollutant is more environmentally beneficial. In the case of LNB, the slight increase in CO is offset by the decrease in NO_x. In the 2002 regulations, EPA specifically listed LNB as an acceptable PCP. Additionally, in 2004, Virginia was utilizing a July 19, 1999, Policy Memo signed by the then DEQ Air Director, John Daniel titled "Incidental CO Emission Increases from Utility Control Efforts" which allows a source the option of not obtaining a permit for the increase of CO as a result of installing LNB. Although the D.C. Circuit Court vacated the PCP provision of the 2002 regulations on June 24, 2005, at the time the actions took place, PCPs were acceptable both under the federal regulations and state policy.

Installation of Separated Over-Fired Air (SOFA)

The installation of SOFA was also required as a result of the federal Consent Decree. SOFA was installed on units 3, 4, & 5 in February 2005. SOFA is also control equipment that reduces NO_x but may cause an increase in CO and VOCs. As with LNB, the PCP portion of the federal NSR reform regulations was still in effect. In addition, and more importantly to the state program, the DEQ policy specifically addressing incidental CO increases as a result of installing NO_x controls was being implemented. The DEQ policy is not limited to LNB. Although it is not specifically listed in the federal regulations as a PCP, it is reasonable to conclude that any subsequent decrease in NO_x would be considered more environmentally beneficial than any slight increase in CO. Regarding VOCs, based on calculations of potential increase in VOC emissions as a result of adding SOFA, it was determined there would be a maximum potential increase of 20.71 tpy. This was calculated using a worse case scenario of future potential to emit of all five boilers at 8760 (28.7 tpy) and subtracting the 2002 – 2003 baseline actual emissions of 23.96 tpy VOC. (2004 was not deemed as a representative year since the facility was shut down part of the year for installation of controls.) The difference of

4.74 tpy is below the significance level of 40 tpy as well as the 25 tpy significance level in a non-attainment area. Therefore, it was determined that no permit action was necessary for the installation of SOFA.

Installation of Trona

The installation of Trona was required by the June 1, 2006, EPA Administrative Consent Order (ACO). The Trona system was installed in February 2005. The Trona system was installed to decrease the SO₂ emissions but it was evaluated for a possible increase in particulate emissions that could have triggered major NSR. Since the installation of Trona, stack testing was conducted to determine if adding Trona results in an increase of PM from the stacks. The stack test showed that adding Trona actually results in a decrease of emissions from the stacks. The Trona system is enclosed and therefore no fugitive emissions are predicted to result from the unloading and injection processes. Additionally, particulate fugitives from the ash handling and road dust were evaluated. Based on the submitted permit application, there is a projected increase of total fugitive PM of approximately 5 tpy as a result of installing the Trona system. Part of the Federal Consent Decree required PRGS to implement controls to reduce PM emissions. This included: 1) Bottom Ash and Fly Ash Silo Vent Secondary Filtration; 2) Coal Pile Wind Erosion and Dust Suppression; 3) Coal Stackout Conveyor Dust Suppression; 4) Ash Loader Upgrade; 5) Ash Loading System Dust Suppression; 6) Coal Railcar Unloading Dust Suppression; 7) Settled Dust Study; and 8) Truck Washing Facility. The estimated reduction of PM emissions from these projects was estimated to be 48 tpy. Several of these projects have already been completed at the facility. The large decrease in PM emissions from these projects would offset the estimated emissions increase resulting from the installation of the Trona system. Therefore, it was determined that no permit action was necessary for the installation of the Trona System.

Conclusion

In conclusion, VADEQ made the determination that none of these three past actions would have triggered Major NSR.

Enclosures:

Mirant Major Source Timeline

VADEQ Policy – “Incidental CO Emission Increases from Utility NO_x Control Efforts”

Calculated VOC Emissions

4/27/07

Calculated VOC Emissions from Adding Control Equipment Mirant Potomac River Generating Station


The VOC emissions were evaluated in relation to the Trona and SOFA projects. By default the baseline evaluation would have been no LNB and no SOFA (2002 and 2003 baseline determination) and the post LNB and SOFA installations (FPTE determinations for the SOFA and Trona). The following table provides the information on these emissions.

| Calculated VOC Emissions | | | | | | |
|--|---------------------|---------------------|---------------------|---------------------|---------------------|--------------------|
| Condition | Unit 1 (tons/yr) | Unit 2 (tons/yr) | Unit 3 (tons/yr) | Unit 4 (tons/yr) | Unit 5 (tons/yr) | TOTAL (tons/yr) |
| Pre LNB/SOFA (2002- 2003 baseline) | 5.45 | 5.74 | 7.66 | 7.96 | 8.34 | 35.15 |
| Post LNB/SOFA including Trona Injection (PTE) | 9.66 | 9.66 | 9.57 | 9.57 | 9.57 | 48.03 |

- The Pre LNB/SOFA emissions are the actual emissions reported for the 2002 and 2003 baseline years.
- The Post LNB/SOFA emissions are the projected emissions assuming 8,760 hours/yr and with Trona injection.
- The increase in emissions is 12.88 tons/yr which is less than both the significances levels for both PSD (40 tons/yr) and non-attainment (25 tons/yr).

DEPARTMENT OF ENVIRONMENTAL QUALITY
INTRA-AGENCY MEMORANDUM

TO : Karen J. Sismour, Regional Permit Manager, TRO

FROM :  John M. Daniel, Jr., PE, DEE, Director, Division of Air Program Coordination

SUBJECT : Incidental CO Emission Increases from Utility NOx Control Efforts

DATE : July 19, 1999

The decision to permit incidental emission increases of carbon monoxide resulting from required NOx control efforts at electric utility power plants should be left to the owner. No compliance or enforcement efforts should be directed against any facility choosing not to seek a permit for such increases.

Our permit rule (9 VAC 5-80-1100) addresses such issues by excluding the addition of pollution control systems from the definition of "modification". While this does not strictly apply to major modifications under the PSD or nonattainment provisions, such increases are exempted under federal regulations in the form of the "WEPCO Rule" (57 FR 32314). Further, EPA issued a guidance document July 1, 1994, (John S. Seitz, Director EPA OAQPS, memo titled "Pollution Control Projects and New Source Review (NSR) Applicability"; see electronic file located at K:\AGENCY\EPABULL\AIR\GUIDANCE\PCPGUIDE.WPS) which extended the concept of the pollution control project exclusion to non-utility facilities. Our lack of adoption of the WEPCO rule is simply a matter of timing. We had intended to incorporate it at the same time we adopted changes to major source permit rules following EPA's adopting its new source review reform package. Unfortunately, that reform effort stalled. In hindsight, we probably should have adopted our version of the WEPCO rule separately.

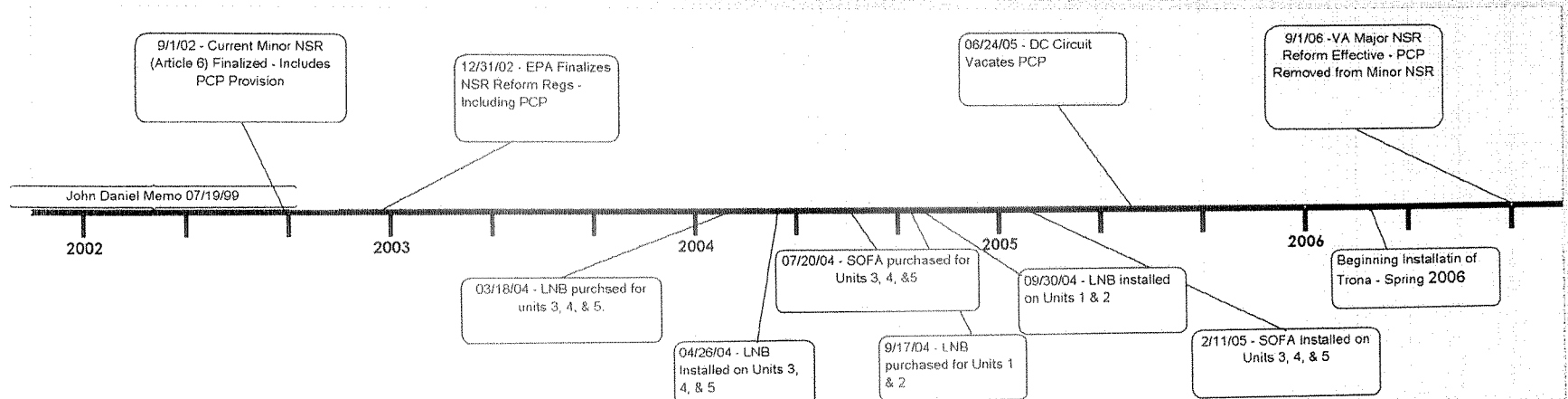
While the July 1, 1994, EPA document does say it is for non-utility facilities only, it also mentions that for years prior EPA had exempted pollution control projects from major source permit requirements on a case by case basis. In that vein, I consider all changes made at Virginia utility plants solely to comply with tighter NOx emission limits imposed by us to qualify for exclusion from both minor and major modification permit requirements as far as increases in carbon monoxide emissions are concerned. The trade-off of modest amounts of CO for substantial amounts of NOx is clearly beneficial from an environmental standpoint.

However, should a utility feel uncomfortable with this determination and insist on obtaining a PSD permit for the CO increase, I would reluctantly say to go ahead and process the application.

cc: Regional Directors
Director, Office of Enforcement Coordination
Director, Office of Air Regulatory Development
Director, Office of Air Permit Programs

DEQ-1B-02579

Major NSR Timeline for Mirant



John Daniel's July 19, 1999, memo was based on the July 1, 1994 John Seitz memo allowing Pollution Control Projects (PCP)
Article 6 PCP regulations required the source to get a permit

Mirant

Assessment of ESP to Bag House Conversion at Potomac River

Potomac River Units 1-5 consists of two 88 MW (1 & 2) and three 102 MW (3, 4, & 5) units. Each unit is equipped with a hot side electrostatic precipitator followed by a cold side precipitator. This document summarizes past findings investigating the performance improvements and costs associated with replacing the existing cold-side precipitators with bag houses. Although the electrical output of Units 1 and 2 is less than the output of Units 3 – 5, the amount of coal feed and flue gas generated is greater because these older units 1 and 2 are not as thermodynamically efficient as the newer units 3, 4 and 5.

Performance Issues

The existing combination of a hot-ESP and a cold-ESP on each unit provides excellent particulate matter removal. In December 2006, Mirant contracted with TRC to conduct particulate emissions testing on Units 2 and 3 (as representative of their sister units) to determine the impact of Trona injection on the ESP performance. Unit 2 had average particulate emission rate of 0.013 - 0.016 lb/mmBtu and Unit 3 had average particulate emission rate of 0.012 – 0.014 lb/mmBtu.

Bag houses typically are being permitted with limits of 0.015 lb/mmBtu. In some situations, companies are seeking guarantees that lower this value further and are at times offered guarantees of 0.012 to 0.013 lb/mmBtu for full-sized baghouses. The PM emission levels achieved for such new facilities do not apply to a complex retrofit such as the one that would be required at Potomac River.

The existing emission rates as measured at Potomac River are very close to the guarantee levels for bag houses, with very little improvement possible. The cost in dollars per ton of particulate removed indicates the project simply would not be economically feasible.

Costs

S&L examined the order of magnitude costs for installation of a bag house replacement in early 2006. The costs for each unit are based on a similar project. At that time the total cost to conduct the replacement was estimated at about 60 million dollars, see Table 1 below. This is based on the higher costs anticipated for installation of the equipment and is not based on quoted values.

Table 1

| | | Unit 1 or 2 | Unit 3, 4, or 5 |
|--|-----------|-------------------|-------------------|
| Gas Flow | acfm | 468,000 | 384,000 |
| A/C ratio | | 6 | 6 |
| Baghouse Cost | \$ | 3,605,000 | 3,159,000 |
| Construction | \$ | 5,353,000 | 4,691,000 |
| Engineering, BOP, Etc. | \$ | 1,912,000 | 1,675,000 |
| Total Typical Installed Cost for Each | \$ | 10,870,000 | 9,525,000 |
| 40% Additional Labor for Retrofit Difficulty | \$ | 2,140,000 | 1,880,000 |
| Total Cost Each | \$ | 13,010,000 | 11,405,000 |
| Total for all 5 Units (2006 estimate) | \$ | 60,235,000 | |

- Notes:**
1. Does not include costs for new ID fan providing additional pressure drop
 2. Does not include costs to upgrade plant electrical infrastructure
 3. Does not include additional costs for Station Ash Handling modifications

Mirant

Assessment of ESP to Bag House Conversion at Potomac River

On September 4, 2007, S&L attended a meeting with Mirant, Hamon (a leading supplier of bag house and ESP equipment to power generation facilities), and consultants to the City of Alexandria, Va. During this meeting 1) the physical arrangement of the existing ESPs were reviewed; 2) the attributes of bag houses and ESPs were reviewed; and 3) the relative degree of difficulty associated with such a retrofit was discussed. At this meeting Hamon indicated that the retrofit would be very difficult to perform in such a tight space as the current cold-ESP location.

After this meeting, Hamon provided a budgetary quote for the supply of bag house equipment (not including installation). They estimated that the equipment supply cost for each bag house would be approximately 3 million dollars, very close to S&L's estimate. Hamon indicated they would guarantee an outlet emission rate of 0.012 lb/mmBtu of particulate emissions. Hamon indicated at the September 4 meeting that this installation would be very difficult and that labor could exceed double a traditional bag house installation. In S&L's 2006 estimate (above) only 40% additional labor was added for a "difficult retrofit". Thus based on the meeting with Hamon, it is likely that the installed costs could exceed 75 million dollars based on budgetary quotations and Hamon's opinion on a very-difficult installation. Furthermore, Hamon suggested that unit outages of as much as 6 months for each unit would likely be required to demolish each ESP and to replace it with a new bag house. From the information provided by Hamon, it is very difficult to **firmlly** identify the labor associated with a retrofit of this type for budgetary purposes. It would require a vendor/construction contractor to carefully assess the full requirements associated with the demolition of the ESP and the reconstruction of the bag house in the tight confines of Potomac River before they could provide a firm-price quotation for such a project.

The cost to replace the ID Fans and modify existing ductwork at Potomac River could add as much as 20 – 25 million dollars to the overall costs. Electrical upgrades and modifications for the ash system to accommodate this bag house have not been fully evaluated but could add \$15 - \$20 million to the project.

Table 2 reflects the new estimate reflecting the most current understanding of total costs

\$60M plus \$15 M for difficulty = \$75 M plus \$20M for fans and other plant modifications, but not including upgrades to the auxiliary power systems.

Table 2

| | | Unit 1 or 2 | Unit 3, 4, or 5 |
|---|-----------|-------------------|-------------------|
| Gas Flow | acfm | 468,000 | 384,000 |
| A/C ratio | | 6 | 6 |
| Baghouse Cost | \$ | 3,605,000 | 3,159,000 |
| Construction | \$ | 5,353,000 | 4,691,000 |
| Engineering, BOP, Etc. | \$ | 1,912,000 | 1,675,000 |
| Total Typical Installed Cost for Each | \$ | 10,870,000 | 9,525,000 |
| Additional Labor for Retrofit Difficulty | \$ | 5,376,000 | 4,723,000 |
| Total Cost Each | \$ | 16,246,000 | 14,248,000 |
| Total for all 5 Units (2006 estimate) | \$ | 75,236,000 | |
| Notes: 1. Does not include costs for new ID fan providing additional pressure drop | | | |
| 2. Does not include costs to upgrade plant electrical infrastructure | | | |
| 3. Does not include additional costs for Station Ash Handling modifications | | | |

per acre total volume by ground or 5 gallons of spray solution per acre by air.

Alabama's and Mississippi's 1994 requests for the use of Pirate to control the BAW on cotton were denied due to the risk of unreasonable adverse effects to non-target birds, aquatic organisms and the environment. Alabama has proposed a 75 foot buffer between cotton fields treated with Pirate and aquatic areas to mitigate these concerns.

Tebufenozide, as either the technical or the 2F formulation, produces minimal to no toxicity following acute exposures. Following subchronic or chronic exposure, tebufenozide does produce organ toxicity after multiple exposures at high doses to laboratory animals. The primary target organ for toxicity is the hemopoietic system and the toxicity was characterized as a regenerative anemia. Tebufenozide produced marginal reproductive effects following multiple exposures of very high doses to rats and was found to be moderately toxic to aquatic and aquatic invertebrate organisms and highly toxic to oysters.

This notice does not constitute a decision by EPA on the applications themselves. The regulations governing section 18 require that the Agency publish notice of receipt in the **Federal Register** and solicit public comment on an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient not contained in any currently registered pesticide) [40 CFR 166.24 (a)(1)]. Pirate is a new chemical.

A record has been established for this notice under docket number "[OPP-180974]" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice, as well as the public version, as described above will be kept in paper form.

Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above. The Agency will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Alabama Department of Agriculture, Mississippi Department of Agriculture and Commerce, Louisiana Department of Agriculture and Forestry, Tennessee Department of Agriculture and the Arkansas State Plant Board.

List of Subjects

Environmental protection, Pesticides and pests, Crisis exemptions.

Dated: June 23, 1995.

Peter Caulkins

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 95-16555 Filed 7-6-95; 8:45 am]

BILLING CODE 6560-50-F

[OPP-36140C; FRL-4957-9]

Inert Ingredients in Pesticide Products; Reclassification of Certain List 3 Inert Ingredients to List 4B

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is issuing a list of inert ingredients formerly considered to be inert ingredients of unknown toxicity (List 3) for which it now has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment and can therefore be reclassified to List 4B.

EFFECTIVE DATE: July 7, 1995.

ADDRESSES: By mail, submit written comments identified by the document control number to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person, deliver comments to: Rm. 1132, Crystal Mall Bldg. #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this

document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number, [OPP-36140C]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Support Branch, Registration Division (7505W), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, 6th Floor, Arlington, VA 22202; (703)-308-8811; e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA announced its policy on toxic inert ingredients in pesticide products in the **Federal Register** of April 22, 1987 (52 FR 13305). Through its policy, EPA encourages the use of the least toxic inert ingredients available and requires the development of data necessary to determine the conditions of safe use of products that contain toxic inert ingredients. In developing this policy, EPA categorized inert ingredients into the following four lists according to toxicity:

List 1—Inerts of toxicological concern.

List 2—Potentially toxic inerts, with high priority for testing.

List 3—Inerts of unknown toxicity.

List 4—Inerts of minimal concern.

In the **Federal Register** of November 22, 1989 (58 FR 48314), EPA issued a

notice announcing some modifications to the previously published Lists 1 and 2. In that notice, EPA also noted that List 4 was being divided into two parts. The original List 4 became List 4A, representing minimal risk inert ingredients. List 4B was created to represent inert ingredients for which EPA has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment. EPA subsequently issued List 4A in the *Federal Register* of September 28, 1994 (59 FR 49400).

As a part of its initial review of the inert ingredients originally categorized as List 3, EPA has identified 146 inert ingredients that merit reclassification to List 4B. The basis for this reclassification is as follows:

1. On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects.

2. Each of these substances is either approved for use by the U.S. Food and Drug Administration as (a) a direct food additive under 40 CFR part 172 or (b) a polymer considered to not present an unreasonable risk on the basis of its conformance with the criteria given in the polymer exemption rule at 40 CFR 723.250. The polymer exemption rule exempts selected low-risk polymers from part or all of the premanufacture notification provisions of section 5 of the Toxic Substances Control Act (TSCA).

3. These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.

A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.

This reclassification is expected to be the first in a series of actions related to the disposition of inert ingredients currently on Lists 2 and 3. EPA is continuing its review of other List 2 and List 3 inert ingredients under the inerts strategy and, following its assessment, will make further determinations regarding inert ingredient categorization.

LIST 4B.—INERT INGREDIENTS

| CAS Reg. No. | Chemical name |
|--------------|--|
| 57-55-6 | Propylene glycol |
| 67-63-0 | Isopropyl alcohol |
| 71-36-3 | 1-Butanol |
| 80-56-8 | alpha-Pinene |
| 91-53-2 | ethoxyquin |
| 94-13-3 | Propyl p-hydroxybenzoate |
| 98-86-2 | Acetophenone |
| 99-76-3 | Methyl p-hydroxybenzoate |
| 102-76-1 | Glyceryl triacetate |
| 106-97-8 | n-Butane |
| 111-27-3 | 1-Hexanol |
| 111-70-6 | 1-Heptanol |
| 112-30-1 | 1-Decanol |
| 120-72-9 | 1H-Indole |
| 123-95-5 | Butyl stearate |
| 124-07-2 | Octanoic acid |
| 124-10-7 | Methyl tetradecanoate |
| 139-44-6 | Glyceryltris (12-hydroxystearate) |
| 141-78-6 | Ethyl acetate |
| 151-21-3 | Dodecyl sulfate, sodium salt |
| 527-07-1 | Gluconic acid, sodium salt |
| 527-09-3 | Cupric gluconate |
| 533-96-0 | Sodium sesquicarbonate |
| 860-22-0 | FD & C Blue No. 2 |
| 868-18-8 | Sodium tartrate |
| 1302-42-7 | Sodium aluminate |
| 1310-58-3 | Potassium hydroxide |
| 1310-73-2 | Sodium hydroxide |
| 1338-41-6 | Sorbitan monostearate |
| 1343-98-2 | Silicic acid |
| 7558-79-4 | Disodium phosphate |
| 7722-88-5 | Diphosphoric acid, tetrasodium salt |
| 7722-88-5 | Tetrasodium pyrophosphate |
| 7664-93-9 | Sulfuric acid |
| 7758-16-9 | Sodium acid pyrophosphate |
| 7784-25-0 | Aluminum ammonium sulfate |
| 7785-87-7 | Manganese sulfate |
| 8009-03-8 | Petrolatum |
| 8015-86-9 | Carnauba wax |
| 8050-33-7 | Polyoxyethylene ester of rosin |
| 8061-51-6 | Lignosulfonic acid, sodium salt |
| 8061-52-7 | Lignosulfonic acid, calcium salt |
| 9002-89-5 | Polyvinyl alcohol |
| 9002-92-0 | Polyoxyethylene dodecyl mono ether |
| 9003-06-9 | Acrylamide-acrylic acid resin |
| 9003-07-0 | Polypropylene |
| 9003-11-6 | Polyoxyethylene-polyoxypropylene copolymer |

LIST 4B.—INERT INGREDIENTS—Continued

| CAS Reg. No. | Chemical name |
|------------------|---|
| 9003-49-0 | Polymerized butyl acrylate |
| 9003-55-8 | Butadiene-styrene copolymer |
| 9004-62-0 | 2-Hydroxyethyl cellulose |
| 9004-64-2 | Cellulose, 2-hydroxypropyl ether |
| 9004-65-3 | 2-Hydroxypropyl methyl cellulose |
| 9004-67-5 | Methyl cellulose |
| 9004-81-3 | Polyoxyethylene monolaurate |
| 9004-82-4 | Dodecanol, ethoxylated, monoether with sulfuric acid, sodium salt |
| 9004-95-9 | Polyoxyethylene monohexadecyl ether |
| 9004-96-0 | Polyoxyethylene monooleate |
| 9004-98-2 | Polyoxyethylene mono(cis-9-octadecenyl) ether |
| 9004-99-3 | Polyoxyethylene monostearate |
| 9005-00-9 | Polyoxyethylene monooctadecyl ether |
| 9005-07-6 | Polyoxyethylene dioleate |
| 9005-08-7 | Polyoxyethylene distearate |
| 9005-37-2 | Propylene glycol alginate |
| 9005-64-5 | Polyoxyethylene sorbitan monolaurate |
| 9005-65-6 | Polyoxyethylene sorbitan monooleate |
| 9005-66-7 | Polyoxyethylene sorbitan monopalmitate |
| 9005-67-8 | Polyoxyethylene sorbitan monostearate |
| 9005-70-3 | Polyoxyethylene sorbitan trioleate |
| 9005-71-4 | Polyoxyethylene sorbitan tristearate |
| 9007-48-1 | Polyglycerol ester of oleic acid |
| 9011-14-7 | Polymethyl methacrylate |
| 9011-29-4 | Polyoxyethylene sorbitol hexastearate |
| 9014-85-1 | Polyethylene glycol ether with ether with 1,4-diisobutyl-1,4-dimethylbutynediol (2:1) |
| 9014-90-8 | Nonylphenol, ethoxylated, monoether with sulfuric acid, sodium salt |
| 9014-92-0 | Polyoxyethylene dodecylphenol |
| 9014-93-1 | Polyoxyethylene dinonylphenol |
| 9016-45-9 | Polyoxyethylene nonylphenol |
| 9036-19-5 | Polyoxyethylene (1,1,3,3-tetramethylbutyl) phenyl ether |
| 9038-29-3 | Oxirane, methyl-, polymer with oxirane, decyl ether |
| 9038-95-3 | Polyethylene-polypropylene glycol, monobutyl ether |
| 9081-17-8 | Nonylphenol, ethoxylated, monoether with sulfuric acid |
| 9084-06-4 | Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt |
| 10124-56-8 | Sodium hexametaphosphate |
| 12173-47-6 | Hectorite |
| 25231-21-4 | Polyoxypropylene monostearyl ether |
| 25322-68-3 | Polyethylene glycol |
| 25322-69-4 | Polypropylene glycol |
| 25496-72-4 | Glyceryl monooleate |
| 25719-52-2 | Dodecyl 2-methylacrylate polymer |
| 25719-60-2 | beta-Pinene homopolymer |
| 26027-38-3 | p-Nonylphenol, ethoxylated |
| 26183-44-8 | Dodecyl alcohol, ethoxylated, monoether with sulfuric acid |
| 26183-52-8 | Polyoxyethylene monodecyl ether |
| 26266-57-9 | Sorbitan monohexadecanoate |
| 26635-76-7 | Glycols, polyethylene, mono(oleylamines)- ethyl ester |
| 26636-39-5 | Polyoxyethylene monoicosyl ether |
| 26636-40-8 | Polyoxyethylene docosyl ether |
| 26915-70-8 | Tridecanol, ethoxylated, phosphate ester |
| 27306-79-2 | Polyoxyethylene monotetradecyl ether |
| 31566-31-1 | Glyceryl monostearate |
| 31800-88-1 | Octyloxypoly(ethyleneoxy)ethyl phosphate |
| 37280-82-3 | Polyoxyethylene polyoxypropylene phosphate |
| 37286-64-9 | Polyoxypropylene monomethyl ether |
| 37340-60-6 | Nonylphenol, ethoxylated, phosphate ester, sodium salt |
| 39464-64-7 | Dinonylphenol, ethoxylated, phosphated |
| 41928-09-0 | Polyethylene glycol ether with 2,2'-methylenebis(4-(tert-octyl)phenol) (2:1) |
| 50769-39-6 | Butylpolyethoxyethanol esters of phosphoric acid |
| 51609-41-7 | 4-Nonylphenol, ethoxylated, phosphate ester |
| 51617-79-9 | Polyoxyethylene octadecylphenol |
| 51811-79-1 | Nonylphenol, ethoxylated, phosphate ester |
| 52503-15-8 | Polyethylene glycol nonylphenyl ether phosphate potassium salt |
| 54116-08-4 | Sodium tridecylpoly(oxyethylene) sulfate |
| 55069-68-6 | Polyethylene glycol hexaether with sorbitol, diester with dodecanoic and oleic acids |
| 56388-96-6 | Poly(oxyethylene)tridecylacetic acid |
| 57171-56-9 | Polyoxyethylene sorbitol hexaoleate |
| 57451-03-3 | Nonylphenol, ethoxylated, monoether with sulfuric acid, triethanolamine salt |
| 59139-23-0 | Polyethylene glycol nonylphenyl ether phosphate ethanolamine salt |
| 60828-78-6 | 2,6,8-Trimethyl-4-nonylpolyethylene glycol ether |
| 60864-33-7 | Benzyl ether of 1,1,3,3-tetramethylbutyl phenoxypolyethoxy ethanol |

LIST 4B.—INERT INGREDIENTS—Continued

| CAS Reg. No. | Chemical name |
|------------------|---|
| 60874-89-7 | Polyethylene glycol ether with methylenebis(diarylphenol) |
| 61725-89-1 | Oxirane methyl-, polymer with oxirane, tridecyl ether |
| 61788-60-1 | Methyl esters of cottonseed oil |
| 61790-90-7 | Fatty acids, tall-oil, hexaester with sorbitol, ethoxylated |
| 61791-12-6 | Castor oil, ethoxylated |
| 61791-23-9 | Soybean oil, ethoxylated |
| 61791-26-2 | Polyethoxylated tallowamine |
| 61827-84-7 | Oxirane, methyl-, polymer with oxirane, octyl ether |
| 63089-86-1 | Polyoxyethylene sorbitol tetraoleate |
| 63393-89-5 | Coumarone - indene resin |
| 64754-90-1 | Chlorinated polyethylene |
| 66070-87-9 | Polyglyceryl phthalate ester of coconut oil fatty acid |
| 67922-57-0 | Polyethylene glycol nonylphenyl ether phosphate magnesium salt |
| 68131-40-8 | Alcohols, C12-15, polyethoxylated |
| 68187-71-3 | Calcium salts of tall-oil fatty acids |
| 68333-69-7 | Rosin, maleated, polymer with pentaerythritol |
| 68425-44-5 | Amides, coco, N-(hydroxyethyl), ethoxylated |
| 68441-17-8 | Oxidized polyethylene |
| 68458-49-1 | Polyphosphoric acids, esters with polyethylene glycol nonylphenyl ether |
| 68526-94-3 | Alcohols, C12-20, ethoxylated |
| 68646-20-4 | Sorbitol-tall oil fatty acid sesquiesther, ethoxylated |
| 68650-09-9 | Fatty acids, tall-oil, mixed esters with glycerol and polyethylene glycol |
| 68891-29-2 | Alcohols, C8-10, ethoxylated, monoether with sulfuric acid, ammonium salt |
| 69227-21-0 | Alcohols, C12-18, ethoxylated propoxylated |
| 70632-06-3 | Alcohols, C12-15, ethoxylated, carboxylated, sodium salts |
| 71012-10-7 | Oleic acid, 2-(2-(2-(2-hydroxyethoxy)ethoxy)ethoxy)ethyl ester |
| 97043-91-9 | Alcohols, C9-16, ethoxylated |

A record has been established for this rulemaking under docket number [OPP-36140C] (including any comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing.

The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping.

Dated: June 23, 1995.

Peter Caulkins,
Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 95-16556 Filed 7-6-95; 8:45 am]

BILLING CODE 6560-50-F

[OPP-66214; FRL 4961-5]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations.

DATES: Unless a request is withdrawn by October 5, 1995, orders will be issued cancelling all of these registrations.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location for commercial courier delivery and telephone number: Room 216, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-5761; e-mail: hollins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, provides that a pesticide registrant may, at any time, request that any of its pesticide registrations be cancelled. The Act further provides that EPA must publish a notice of receipt of any such request in the *Federal Register* before acting on the request.

II. Intent to Cancel

This Notice announces receipt by the Agency of requests to cancel some 31 pesticide products registered under section 3 or 24(c) of FIFRA. These registrations are listed in sequence by registration number (or company number and 24(c) number) in the following Table 1.

§582.1666 Propylene glycol.

(a) *Product.* Propylene glycol.

(b) *Conditions of use.* This substance is generally recognized as safe (except in cat food) when used in accordance with good manufacturing or feeding practice.

[41 FR 38657, Sept. 10, 1976, as amended at 61 FR 19544, May 2, 1996]

§582.1685 Rennet.

(a) *Product.* Rennet (rennin).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1711 Silica aerogel.

(a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of antifoaming agents in accordance with good manufacturing or feeding practice.

§582.1721 Sodium acetate.

(a) *Product.* Sodium acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1736 Sodium bicarbonate.

(a) *Product.* Sodium bicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1742 Sodium carbonate.

(a) *Product.* Sodium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1745 Sodium carboxymethylcellulose.

(a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95

carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25 °C.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1748 Sodium caseinate.

(a) *Product.* Sodium caseinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1751 Sodium citrate.

(a) *Product.* Sodium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1763 Sodium hydroxide.

(a) *Product.* Sodium hydroxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1775 Sodium pectinate.

(a) *Product.* Sodium pectinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1781 Sodium aluminum phosphate.

(a) *Product.* Sodium aluminum phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§582.1792 Sodium sesquicarbonate.

(a) *Product.* Sodium sesquicarbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when

§ 582.1804

used in accordance with good manufacturing or feeding practice.

§ 582.1804 Sodium potassium tartrate.

(a) *Product.* Sodium potassium tartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1901 Triacetin.

(a) *Product.* Triacetin (glyceryl triacetate).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1973 Beeswax.

(a) *Product.* Beeswax (yellow wax).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1975 Bleached beeswax.

(a) *Product.* Bleached beeswax (white wax).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.1978 Carnauba wax.

(a) *Product.* Carnauba wax.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Subpart C—Anticaking Agents

§ 582.2122 Aluminum calcium silicate.

(a) *Product.* Aluminum calcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt

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in accordance with good manufacturing or feeding practice.

§ 582.2227 Calcium silicate.

(a) *Product.* Calcium silicate.

(b) *Tolerance.* 2 percent and 5 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used at levels not exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing or feeding practice.

§ 582.2437 Magnesium silicate.

(a) *Product.* Magnesium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

§ 582.2727 Sodium aluminosilicate.

(a) *Product.* Sodium aluminosilicate (sodium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing or feeding practice.

§ 582.2729 Hydrated sodium calcium aluminosilicate.

(a) *Product.* Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing or feeding practice.

§ 582.2906 Tricalcium silicate.

(a) *Product.* Tricalcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing or feeding practice.

Subpart D—Chemical Preservatives

§ 582.3013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

§ 184.1792

2101 Constitution Ave. NW., Washington DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter and a flavoring agent as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; cheeses as defined in § 170.3(n)(5) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; jams and jellies as defined in § 170.3(n)(28) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13142, Apr. 3, 1984]

§ 184.1792 Sodium sesquicarbonate.

(a) Sodium sesquicarbonate ($\text{Na}_2\text{CO}_3 \cdot \text{NaHCO}_3 \cdot 2\text{H}_2\text{O}$, CAS Reg. No. 533-96-0) is prepared by: (1) Partial carbonation of soda ash solution followed by crystallization, centrifugation, and drying; (2) double refining of trona ore, a naturally occurring impure sodium sesquicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 299, which is incorporated by reference. Copies are avail-

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able from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in cream at levels not to exceed current good manufacturing practice. Current good manufacturing practice utilizes a level of the ingredient sufficient to control lactic acid prior to pasteurization and churning of cream into butter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52443, Nov. 18, 1983]

§ 184.1801 Sodium tartrate.

(a) Sodium tartrate ($\text{C}_4\text{H}_4\text{Na}_2\text{O}_6 \cdot 2\text{H}_2\text{O}$, CAS Reg. No. 868-18-8) is the disodium salt of L-(+)-tartaric acid. It occurs as transparent, colorless, and odorless crystals. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 303, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

2. Amend § 288.7(d)(1) by adding a proviso to read as follows:

(d) For Category A transportation services on and after

(1) Passengers, 7.044 cents per passenger-mile: *Provided*, That a carrier may perform Category A passenger services at a rate per passenger-mile which, when applied to the mileage between specific points in accordance with subparagraph (3) of this paragraph, produces a product fare equal to a published, unrestricted, one-way, passenger tariff fare that is in fact available to the general public for equivalent services, in the event that the Category A rate per passenger-mile, specified above, would result in a higher charge than such published tariff.

(2) * * *

(Secs. 204, 403 and 416 of the Federal Aviation Act of 1958, as amended; 72 Stat. 743, 758 and 771, as amended; 49 U.S.C. 1324, 1373 and 1386).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

APPENDIX I—SUMMARY OF SEATING CONFIGURATIONS IN CHARTER AND SCHEDULED SERVICES

| Aircraft type | Carrier | Charter service | Scheduled service |
|---------------|------------|-------------------------------|-------------------|
| B-747..... | AA..... | 364-424..... | 343 |
| | BN..... | 356..... | 356 |
| | DL..... | 370..... | 370 |
| | NW..... | 369, 375..... | 369 |
| | PA..... | 373, 381, 400, 408 437, 453. | 373, 400 |
| | TW..... | 353..... | 363 |
| | UA..... | 342, 374..... | 342 |
| | World..... | 357, 395, 411, 423, 445, 461. | — |
| L-1011..... | DL..... | 256, 264..... | 256 |
| | EA..... | 256..... | 261 |
| DC-10-10..... | AA..... | 240..... | 240 |
| | UA..... | 242, 259..... | 241 |
| DC-30..... | NA..... | 283..... | 269 |
| | TIA..... | 275, 303, 345, 376. | — |
| DC-40..... | NW..... | 236..... | 236 |

WIDE-BODY AIRCRAFT SEATING DENSITIES PER MANUFACTURER'S SPECIFICATION

| Aircraft type | Number of seats |
|---------------------------|-----------------|
| B-747100/200B/200C..... | 374-500 |
| DC-10-30/40..... | 250-380 |
| L-1011-1/100/200/250..... | 250-400 |

[FR Doc. 78-16235 Filed 6-12-78; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 10]

[Docket No. 78N-0126]

SEPARATION OF FUNCTIONS AND EX PARTE COMMUNICATIONS

Withdrawal of Proposal and Termination of Rulemaking Proceedings

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposal.

SUMMARY: The Commissioner of Food and Drugs is withdrawing a proposal to establish rules concerning separation of functions and ex parte communications. The proposal is being withdrawn because it has been superseded by more recent procedural regulations.

EFFECTIVE DATE: June 13, 1978.

FOR FURTHER INFORMATION CONTACT:

Richard T. Hunt, Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of March 24, 1972 (37 FR 6107), the Commissioner issued a proposal to establish regulations concerning separation of functions and ex parte communications. The proposal was intended, among other things, to more clearly define permissible and impermissible communication among parties to a public hearing and FDA officials, employees, and attorneys.

In the FEDERAL REGISTER of January 25, 1977 (42 FR 4680), the Commissioner adopted new comprehensive administrative practices and procedures that encompassed the issues of separation of function and ex parte communications.

Accordingly, the Commissioner announces that the proposal published in the FEDERAL REGISTER of March 24, 1972 (37 FR 6107) is now superseded and is hereby withdrawn.

This withdrawal is issued under the Federal Food, Drug, and Cosmetic Act (sec. 701, 52 Stat. 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 371)) and under the Administrative Procedure Act (secs. 4.5, 60 Stat. 238, 239 as amended (5 U.S.C. 553, 554)) and under authority delegated to the Commissioner (21 CFR 5.1).

Dated: June 5, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.
[FR Doc. 78-16089 Filed 6-12-78; 8:45 am]

[1505-01]

[21 CFR Parts 182, 184]

[Docket No. 78N-00161]

INOSITOL

Proposed Affirmation of GRAS Status as a Direct Human Food Ingredient

Correction

In FR Doc. 78-13715 appearing at page 22056 in the issue for Tuesday, May 23, 1978, make the following corrections:

(1) On page 22057, in the first column, in the next to last line, "O-B-D-galactopyranosyl myo-inositol" should read "O-β-D-galactopyranosyl myo-inositol."

(2) On page 22058, in the middle column, in § 184.1341(a), in the third line, delete the between "trans-4," and "6-cyclohexanhexol."

[4110-03]

[21 CFR Parts 182, 184, 186]

[Docket No. 78N-00711]

CARBONATES AND BICARBONATES

Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This is a proposal to affirm the generally recognized as safe (GRAS) status of calcium carbonate, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium sesquicarbonate as direct human food ingredients, and of sodium bicarbonate and sodium carbonate as indirect human food ingredients. The safety of these ingredients has been evaluated under a comprehensive safety review being conducted by the agency. The proposal would list calcium carbonate, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium sesquicarbonate as direct food substances affirmed as GRAS, and sodium bicarbonate and sodium carbonate as indirect food substances affirmed as GRAS.

DATE: Comments by August 14, 1978.

ADDRESS: Comments (preferably four copies) to the Hearing Clerk (HFC-20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION:

The Commissioner of Food and Drugs has issued several notices and proposals (see the FEDERAL REGISTER of July 26, 1973 (38 FR 20040)) initiating a comprehensive safety review of human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction. Under this review, which is being conducted by the Food and Drug Administration (FDA), the safety of calcium carbonate, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium sesquicarbonate has been evaluated. Under § 170.35 (21 CFR 170.35), the Commissioner proposes to affirm the GRAS status of these ingredients. Ammonium bicarbonate, ammonium carbonate, and magnesium carbonate will be considered in other proposals on ammonium and magnesium salts, respectively.

Carbonates and bicarbonates are commonly used in foods as neutralizers and leavening agents. These anions occur in body fluids and tissues as the result of normal metabolic processes and are important in the control of acid-base balance. Their salts are usually colorless or white translucent or transparent crystals, flakes, powders, or granules. Except for calcium carbonate, most of the carbonates used in foods are fairly soluble in water. They may decompose in dry and/or moist air with temperature gradients proportionately influencing the rate of degradation.

Calcium carbonate, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium sesquicarbonate are listed in §§ 182.1191, 182.1613, 182.1619, 182.1736, 182.1742, and 182.1792 (21 CFR 182.1191, 182.1613, 182.1619, 182.1736, 182.1742, and 182.1792), respectively, as multiple purpose GRAS food substances, under regulations published in the FEDERAL REGISTER of November 20, 1959 (24 FR 9368) and subsequently recodified. Calcium carbonate is also listed in § 182.5191 (21 CFR 182.5191) as a nutrient and dietary supplement, under regulations published in the FEDERAL REGISTER of November 20, 1959 (24 FR 9368), and is prior sanctioned for use as a stabilizer in § 181.29 (21 CFR 181.29). Sodium bicarbonate and sodium carbonate are listed in § 182.70 (21 CFR 182.70) for use in cotton and cotton fabrics used

in dry food packaging, under regulations published in the FEDERAL REGISTER of June 10, 1961 (26 FR 5224). Sodium carbonate is also listed in § 182.90 (21 CFR 182.90) for use in paper and paperboard packaging materials, under regulations published in the FEDERAL REGISTER of June 17, 1961 (26 FR 5421).

Certain Federal standards of identity list the use of some bicarbonates and carbonates in food: Calcium carbonate in frozen desserts (Part 135 (21 CFR 135)), cereal flours and related products (Part 137 (21 CFR 137)), and food dressings and flavorings (Part 169 (21 CFR Part 169)); sodium bicarbonate in cereal flours and related products (Part 137), canned vegetables (Part 155 (21 CFR Part 155)), and cacao products (Part 163 (21 CFR Part 163)); sodium carbonate in canned vegetables (Part 155), and cacao products (Part 163); and potassium bicarbonate and potassium carbonate in cacao products (Part 163).

Sodium bicarbonate is cleared by the Meat Inspection Division (MID) of the United States Department of Agriculture, to separate fatty acids and glycerol in rendered fats, and for use as a cooling and retort water treatment agent for prevention of staining exterior surfaces of food cans. Sodium carbonate is cleared by MID to refine rendered fats, to denude mucous membranes from tripe, and as a cooling and retort water treatment agent for prevention of staining exterior surfaces of food cans. The Bureau of Alcohol, Tobacco, and Firearms has cleared calcium carbonate and sodium carbonate under § 240.1051 (27 CFR 240.1051) to reduce excess natural acids in wine. Potassium carbonate and sodium carbonate are regulated as food additives in § 173.310 (21 CFR 173.310) as components of boiler water additives. Calcium carbonate is also regulated as a food additive in § 175.300 (21 CFR 175.300) for use in resinous and polymeric coatings, and in § 177.1600 (21 CFR 177.1600) for use in polyethylene resins, carboxyl modified.

A representative cross-section of food manufacturers was surveyed to determine the specific foods in which carbonates and bicarbonates have been used and the levels of usage. Information from surveys of consumer consumption was obtained and combined with the manufacturing information to obtain an estimate of consumer exposure to these ingredients. The total amounts of these ingredients used by the United States food industry in 1970 were 33 million pounds of calcium carbonate, 37,000 pounds of potassium bicarbonate, 4 million pounds of potassium carbonate, 95 million pounds of sodium bicarbonate

and 35 million pounds of sodium carbonate. No food-use data were reported for sodium sesquicarbonate in these surveys. From industry sources, however, it was reported that 712,000 pounds of sodium sesquicarbonate were sold in 1970. The total amount of carbonates and bicarbonates (including ammonium bicarbonate and ammonium carbonate) used in food in 1970 is more than double that used in 1960.

The carbonates and bicarbonates have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered: (1) chemical toxicity; (2) occupational hazards; (3) metabolism; (4) reaction products; (5) degradation products; (6) any reported carcinogenicity, teratogenicity, or mutagenicity; (7) dose response; (8) reproductive effects; (9) histology; (10) embryology; (11) behavioral effects; (12) detection; and (13) processing. A total of 874 abstracts on carbonates was reviewed and 70 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

The scientific literature review shows, among other studies, the following information as summarized in the report of the Select Committee on GRAS Substances (the Select Committee), selected by the Life Sciences Research Offices of the Federation of American Societies for Experimental Biology:

The biochemical role of the bicarbonate salts has been studied for over 50 years. Investigations using radioisotope procedures have educed extensive information concerning their absorption, metabolism, excretion, and control of acid-base balance of the body. The Select Committee has found few reports of experiments expressly designed to determine the oral toxicity, mutagenicity, teratogenicity or carcinogenicity of the various carbonate compounds. Knowledge of specific toxic levels and the effects of long-term feeding on various species of animals is lacking.

Orally administered to an unstated number of rats, potassium carbonate had an LD₅₀ of 1.87 g per kg. Potassium bicarbonate caused an 80 percent increase in intercalated cells of the collecting tubules of the kidneys of rats 4.5 hours after intubation of 345 mg.

Ten chicks fed potassium bicarbonate as a 3 percent supplement to a basal diet for up to four weeks showed no signs of illness, although two chicks developed white liver nodules. In other animal studies, 11 lambs fed a concentrated ration supplemented by 2 percent of 1:1 mixture of sodium and potassium bicarbonate for 59 days showed an increase in weight gain, feed consumption and feed efficiency.

Potassium carbonate in *in vitro* microbial assays was not mutagenic in assays with *Saccharomyces cerevisiae*, strain D4 and

Salmonella typhimurium, strains TA-1535, TA-137, and TA-1538. Tissue homogenates for plate and suspension activation assays were prepared from liver, lungs and testes of mice, rats and monkeys.

Teratologic evaluation of potassium carbonate was performed in mice and rats. The administration of up to 290 mg per kg to pregnant mice and up to 180 mg per kg to pregnant rats for 10 consecutive days (day 6 through day 15 of gestation) had no clearly discernible effect on nidation or on maternal or fetal survival. The number of abnormalities seen in either soft or skeletal tissues of the test group did not differ from the number occurring spontaneously in the sham-treated controls.

The acute oral toxicity of sodium bicarbonate was studied in intubated Wistar SPF rats weighing 100 to 150 g. LD₅₀ levels reported were 8.9 g per kg in fed rats, 7.57 g per kg in fasted rats on wire floored cages, and 8.46 g per kg in fasted rats bedded on wood shavings. Dose volume was influential: the LD₅₀ was 8.39 g per kg in fed rats receiving 20 to 25 ml per kg, compared to 5.85 g per kg in fed rats receiving 32 ml per kg. In another study using 200 g rats, the LD₅₀ levels observed at 20 ml per kg and 50 ml per kg were 5.5±0.6 g per kg and 4.85±0.3 g per kg, respectively. Intubation of 290 to 493 mg of sodium bicarbonate caused an 80 percent increase in intercalated cells of the collecting tubules of the kidneys of rats.

The intraperitoneal injection of 18 Ci of sodium [¹⁴C] bicarbonate into CFW mice was followed by assays (after 24 and 48 hours and 1, 2, 4, and 12 weeks) of blood, spleen, liver, kidneys, lungs, brain, jejunum, muscle, skin, hair, and long bones. More than 90 percent of the total radioactivity injected was lost via the respiratory route in one hour. At 24 hours, most of the radioactivity in the blood was in noncarbonate form. Specific activity in long bones paralleled that in the blood for up to 12 weeks. The radioactivity of the compound injected into a pregnant mouse was fixed in the fetal tissues more rapidly than in the maternal tissues. Variable and transient responses in erythrocyte counts and hemoglobin levels in mice to orally administered sodium bicarbonate were reported.

Rapid absorption was demonstrated in rats after intraperitoneal injection of less than one mg sodium [¹⁴C] bicarbonate. Expired radioactivity reached a maximum specific activity within 4 to 10 minutes, and by 13 to 16 minutes the specific activity was reduced by half. In a further study, rats were fasted for 24 hours and given lactate by stomach tube, followed by five intraperitoneal injections of sodium [¹⁴C] bicarbonate made at 30 minute intervals. The animals were sacrificed one-half hour later and about 60 percent of the label was accounted for. The livers were removed and the glycogen extracted; 0.3 to 1.1 percent of the administered carbon-11 was present in the glycogen. Urine contained 1.3 percent of the dose and over 50 percent of the dose was accounted for by respiratory [¹⁴C] carbon dioxide. The authors calculated that one out of eight carbon atoms present in the glycogen was derived from the bicarbonate carbon. Sodium bicarbonate has been reported to affect citrate metabolism in the kidneys or rats. An intraperitoneal injection of 672 mg per kg into four male rats caused a threefold rise in tissue citrate levels of the kidney and a smaller but significant rise in the citrate levels in the liver.

In man, at plasma bicarbonate levels below 24 mM, virtually all bicarbonate en-

tering the renal tubules is reabsorbed. Above this level the excess bicarbonate is excreted. Oral administration of sodium bicarbonate at one g per kg as a single dose increased sodium excretion and decreased blood chloride concentration and urine chloride excretion. These studies demonstrate that the carbonate and bicarbonate ions enter and are constituents of the normal metabolic pathways of man.

As reported in a preliminary paper, two groups of 22 two-week-old chicks were given water containing 0.6 and 1.2 percent sodium bicarbonate for varying periods of time. Those fed the 1.2 percent level developed lesions of gout (kidneys damaged by accumulation of urate crystals with accumulation of water in these organs and other parts of the viscera) as early as the first day. The kidneys of chicks administered 0.6 percent sodium bicarbonate become pale on the first day but did not develop lesions of gout. An autopsy showed that all chicks, fed the higher level of bicarbonate developed urate crystals in their kidneys by the third or fourth days. Mature cockerels were not injured by feeding the 1.2 percent solution, but 24 percent caused clinical signs of gout and death within five days. The investigators inferred that age and severity of lesions were inversely correlated. In another study of poultry, three two-week-old ducklings received 2 percent sodium bicarbonate in their drinking water and died within 3 days; kidney damage was reported.

Intravenous administration of sodium bicarbonate over 7 days for an average total dose of 3.7 g per kg produced no pathological changes in any of 28 rats. The total dose was given in one to seven daily injections, the average being 3.7 injections. The same investigators reported no pathological kidney changes in nine rabbits receiving 2.3 g per kg of sodium bicarbonate intravenously or in four rabbits receiving 6.4 g per kg subcutaneously over a one-week period.

Additional effects on metabolism have been reported in rats and guinea pigs. Intubation of 0.2 to 0.5 g of sodium bicarbonate decreased the amount of liver glycogen in fasted rats within 3 hours. When fed in the diet, it induced increased excretion of β -hydroxybutyric acid and lactic acid in the urine of rats. In the guinea pig, sodium bicarbonate fed for 15 days at a level of 400 mg per kg with ascorbic acid resulted in an increased concentration of ascorbic acid in the adrenals and livers as compared to controls fed ascorbic acid. These observations were apparently not associated with pathologic changes.

The effect of sodium bicarbonate upon gastric secretion was studied in five dogs. Intubation of 75 to 100 mg sodium bicarbonate per kg three times daily increased gastric secretory activity a short time after a meal; later the secretory volume decreased. In a 19 kg dog intravenous injection of 27.4 to 42.5 g of sodium bicarbonate induced alkalosis and caused a decrease in serum calcium, chloride and phosphorus but with a large increase in total base, sodium, and blood bicarbonate. Intravenous addition of sodium chloride did not alter the severity of the alkalosis, and the sodium and total base values were further elevated.

Potassium was retained and ammonia formation decreased in a 25-year-old man who consumed 8.4 g sodium bicarbonate daily (122 mg per kg) for six days. Six adult humans ingested 120 mg per kg of sodium bicarbonate daily for five days. Urine calcium decreased significantly for all six sub-

jects when compared to that of a similar control diet period.

Thirty-three patients with gastric or peptic ulcers were treated via gastric tube with sodium bicarbonate in daily doses of up to 100 g at a constant rate for three weeks. All developed alkalosis as plasma carbon dioxide content rose. Inulin and endogenous creatinine clearances indicated no impairment of renal function. The glomerular filtration rate increased during treatment, but it tended to drop to subnormal and recover to normal levels when therapy stopped. No renal damage was observed. Large amounts of sodium were apparently retained in an expanded extracellular space. Oral administration of large doses (840 mg per kg per day) to an infant for 8 days also caused sodium retention. One 23-year-old patient (54 kg) received a total dose of 3.2 kg sodium bicarbonate over a period of 20 months for treatment of duodenal ulcer, without marked difference in acid-base balance or decrease in urea clearance and with no change in red and white blood cell counts or hemoglobin values.

The effect of oral and intravenous administration of sodium bicarbonate to dogs was studied. One kidney was surgically removed from each dog for comparison of pre- and post-treatment morphology. Nine dogs received gradually increased doses from 5 to 60 g sodium bicarbonate (up to 10 g per kg) per day. Five of these dogs received oral doses for 30 to 114 days. The remaining four dogs received oral doses of sodium bicarbonate daily and intravenous injection each week for a period of 125 to 261 days. Two dogs in the oral dose group survived; the rest died in acute alkalosis. Renal lesions of toxicity were hyperemia, edema and protein precipitation in the tubules. The dogs receiving the intravenous supplement had the greatest renal damage.

In humans, sodium bicarbonate temporarily decreases protease and amylase activity when introduced directly into the jejunum in isotonic solution. Cardiac and respiratory rate increases associated with hard exercise were more pronounced under the influence of sodium bicarbonate fed to adult men as a single dose (100 mg per kg). Marked diuresis occurred during fatigue. Decreased plasma levels and decreased excretion of ascorbic acid in the urine were observed during a two-week study when 15 g of sodium bicarbonate was fed daily to two female subjects on a diet containing 67 mg of ascorbic acid. Drug interactions reported included an increased absorption rate of sulfadiazine when taken with sodium bicarbonate on an empty stomach but sodium bicarbonate apparently delayed absorption of sulfadiazine if given after a meal.

Sodium bicarbonate was not mutagenic in *in vitro* assays with *Salmonella* or *Saccharomyces*. Sodium bicarbonate and sodium carbonate were not teratogenic in mice or rats. Sodium carbonate was neither toxic nor teratogenic in the chick embryo at levels up to 200 mg per kg.

Studies of metabolism and excretion have included intraperitoneal implantation of 0.40 mCi of calcium [⁴⁵C] carbonate as a pellet in a male rat. About 72 percent of the radioactivity was excreted as respiratory carbon dioxide between 2 and 142 hours after implantation (most after 60 hours). About 30 percent of the dose was recovered in unabsorbed pellet. Urinary radioactivity accounted for 0.27 percent and fecal radioactivity for about 0.07 percent of the dose; 1 percent of the absorbed dose was retained

by the tissues. Significant amounts of radioactivity were incorporated into the inorganic fraction of bone and into bone protein, dentin and enamel, as well as in fatty acids, glycerol, hemin, red cell protein, plasma protein, liver and muscle glycogen, muscle protein and the proteins of the testes, thoracic and abdominal viscera; in the kidney, the highest concentration was in the cortex. The same investigators distributed the compound over the peritoneal viscera of a male rat and collected exhaled air. The largest amount of radioactivity in respiratory carbon dioxide was present on the 7th and 8th days; none was detected on the 22nd day.

Calcium [^{14}C] carbonate injected into a rat produced a higher specific activity in the saturated fatty acids than in the unsaturated fatty acids. Similar results were obtained with sodium [^{14}C] carbonate. The carbon-14 content of the carboxyl carbon atoms was twice as high as the average for all fatty acid carbon atoms. Five rats were fed [^{14}C] calcium carbonate for three days at 3 g per kg of feed (0.3 g per kg body weight). All rats remained healthy; calcium-45 was deposited in the femur, demonstrating the availability of calcium in the carbonate form.

In humans it has been reported that calcium carbonate taken orally in single doses from 16 to 200 mg per kg caused a transient rise in blood serum calcium. After 40 g (0.66 g per kg) calcium carbonate was fed daily for 4 days to three adult humans with peptic ulcers, a large reduction of urinary potassium was observed.

Addition of calcium carbonate to the basal diet at levels of 1 and 3 percent resulted in lower tissue iron values in anemic rats; this was interpreted as a disturbance in the normal concentration of inorganic ions in the principal absorptive portions of the digestive tract. Other investigators have shown that low intake of calcium and a high intake of phosphorus can cause impaired iron utilization with anemia. Under some circumstances either calcium salts or phosphate salts may improve iron absorption, while an excess of either may inhibit iron absorption. Calcium carbonate at 7.26 g per pound of flour in an 80 percent bread diet for 10 weeks in anemic rats (about 0.3 g CaCO_3 daily per kg body weight) decreased food consumption and decreased weight gain. Even though the treated diet contained supplemental iron, the iron content of the liver decreased and hemoglobin regeneration was retarded; heart weights increased. It was postulated that the calcium saturated the alimentary mucosal cells, presenting a block to the absorption of iron. The calcium:phosphorus ratio of the experimental diet was about 5:1.

Feeding a cariogenic ration consisting largely of coarsely ground corn supplemented with 3 percent calcium carbonate and 2 to 4 I.U. vitamin D for about four months to three groups of weanling rats resulted in marked reduction of weight gain but had no effect on dental caries incidence.

In humans, the oral administration of calcium carbonate to 28 peptic ulcer patients at a level of 500 mg per kg per day, divided into hourly doses during waking hours for three weeks, resulted in six patients developing hypercalcemia (five within 72 hours) with nausea, vomiting, anorexia, weakness, lethargy, headache, and dizziness. Blood urea nitrogen values increased significantly.

After withdrawal of calcium carbonate the serum calcium values returned to normal.

Calcium retention increased 86.3 percent, and urinary calcium output also increased, when a basal diet providing 1 g calcium daily was supplemented with 2.5 g calcium carbonate and fed to 10 men for 10 days. This provided calcium carbonate at 40 mg per kg and a daily calcium intake of 2 g.

Female Swiss mice were bred after one week on diets which were supplemented by 0.5, 1.0, and 2.0 percent of calcium carbonate. First and second litters were studied. The highest levels of calcium carbonate gave a calcium carbonate intake of about 3 g per kg body weight and a calcium:phosphorus ratio of 2.3:1. This diet significantly lowered the number and total weight of the weanling mice and increased the number and proportion of deaths as compared to a control diet. The control diet provided 0.34 percent calcium and a calcium:phosphorus ratio of 0.70:1. The diet having the highest calcium content caused hypertrophy of the heart and a tendency toward decrease in thymus weight in the weanling rats. These changes were prevented by supplementing the maternal diets with iron. It has been pointed out in another report by the Select Committee that an excess of dietary calcium may precipitate a deficiency of zinc and perhaps certain other trace inorganic elements.

No specific biological information on sodium sesquicarbonate is available to the Select Committee.

All of the available safety information on bicarbonates and carbonates has been carefully evaluated by qualified scientists of the Select Committee. It is the opinion of the Select Committee that:

*** [It] is not aware of any long-term experimental studies on chronic administration of any of the carbonate salts. The results of acute toxicity and short-term feeding experiments are not readily extrapolated in determining toxic levels for carbonate salts consumed by humans. Treatment of gastric or peptic ulcers in patients with large amounts of carbonate salts in various forms has been utilized for many years and only rarely have deleterious results of changes of acid-base balance been reported. When the human respiratory and renal functions are normal, the mechanisms for

disposing of bicarbonate intake in large amounts through excretion appear to be highly efficient.

Studies of mice suggest that large intakes of calcium carbonate may interfere with reproductive performance. Such effects could be indirectly attributable to certain trace nutrient deficiencies. Comparable intake levels of calcium may occur when calcium carbonate is used for therapeutic purposes but the amounts added to foods in normal manufacturing processes are not high enough to be harmful. While the Select Committee is not aware of any studies on sodium sesquicarbonate *per se*, reasoned judgment suggests its biochemical conversion and metabolism would be similar to that of sodium carbonate and bicarbonate.

The Select Committee concludes that there is no evidence in the available information on calcium carbonate, potassium carbonate, potassium bicarbonate, sodium carbonate, sodium bicarbonate, or sodium sesquicarbonate that demonstrates or suggests reasonable grounds to suspect a hazard to the public when used at levels that are now current or that might reasonably be expected in the future. Based upon his own evaluation of available information on these carbonates and bicarbonates, the Commissioner concurs with this conclusion. The Commissioner therefore maintains that no change in the current GRAS status of these ingredients is justified. Ammonium bicarbonate, ammonium carbonate, and magnesium carbonate will be considered in other proposals on ammonium and magnesium salts, respectively.

Copies of the scientific literature review on the carbonates, mutagenic evaluations of potassium carbonate and sodium bicarbonate, teratogenic evaluations of potassium carbonate, sodium bicarbonate, and sodium carbonate, and the report of the Select Committee are available for review at the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161, as follows:

| Title | Ordering No. | Price code | Price ¹ |
|--|---------------|------------|--------------------|
| Carbonates (scientific literature review) | PB-221-231 | A07 | \$7.25 |
| Potassium carbonate (mutagenic evaluation) | PB-245-501/AS | A03 | 4.50 |
| Sodium bicarbonate (mutagenic evaluation) | PB-245-436/AS | A03 | 4.50 |
| Potassium carbonate (teratogenic evaluation) | PB-245-522/AS | A03 | 4.50 |
| Sodium bicarbonate (teratogenic evaluation) | PB-234-871/AS | A03 | 4.50 |
| Sodium carbonate (teratogenic evaluation) | PB-234-868/AS | A03 | 4.50 |
| Carbonates and bicarbonates (Select Committee report). | PB-254-535/AS | A03 | 4.50 |

¹Price subject to change.

This proposed action does not affect the present use of bicarbonate and carbonate salts for pet food.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s),

409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Parts 182, 184, and 186 as follows:

**PART 182—SUBSTANCES GENERALLY
RECOGNIZED AS SAFE**

§ 182.70 [Amended]

1. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by deleting the entries for "Sodium bicarbonate" and "Sodium carbonate."

§ 182.90 [Amended]

2. In § 182.90 *Substances migrating to food from paper and paperboard products* by deleting the entry for "Sodium carbonate."

§§ 182.1191, 182.1613, 182.1619, 182.1736, 182.1742, 182.1792, and 182.5191 [Deleted]

3. By deleting § 182.1191 *Calcium carbonate*, § 182.1613 *Potassium bicarbonate*, § 182.1619 *Potassium carbonate*, § 182.1736 *Sodium bicarbonate*, § 182.1742 *Sodium carbonate*, § 182.1792 *Sodium sesquicarbonate*, § 182.5191 *Calcium carbonate*.

**PART 184—DIRECT FOOD SUBSTANCES AF-
FIRMED AS GENERALLY RECOGNIZED AS
SAFE**

4. In Part 184 by adding new §§ 184.1191, 184.1613, 184.1619, 184.1763, 184.1742, and 184.1792 to read as follows:

§ 184.1191 Calcium carbonate.

(a) Calcium carbonate (CaCO_3 , CAS Reg. No. 471-34-1) is prepared by three common methods of manufacture:

- (1) As a byproduct in the "Lime soda process";
- (2) By replacement of carbon dioxide in the "Carbonation process"; or
- (3) By precipitation of calcium carbonate from calcium chloride in the "Calcium chloride process."

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972), as amended by the first supplement.¹

(c) The ingredient is used in food as an anticaking and free-flow agent as defined in § 170.3(o)(1) of this chapter, dough strengthener as defined in § 170.3(o)(6) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, and syn-

ergist as defined in § 170.3(o)(31) of this chapter.

(d) The ingredient is used in food and infant formulas, in accordance with § 184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.5 percent in baked goods as defined in § 170.3(n)(1) of this chapter, 0.02 percent in nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter, 1.3 percent in breakfast cereals as defined in § 170.3(n)(4) of this chapter, 14 percent in chewing gum as defined in § 170.3(n)(6) of this chapter, 7.5 percent in confections and frostings as defined in § 170.3(n)(9) of this chapter, 0.9 percent in gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter, 1.2 percent in reconstituted vegetables as defined in § 170.3(n)(33) of this chapter, 1.4 percent in soft candy as defined in § 170.3(n)(38) of this chapter, 2.5 percent in sweet sauces, toppings, and syrups as defined in § 170.3(n)(43) of this chapter, 1.4 percent in infant formulas, and 0.3 percent or less in all other food categories.

§ 184.1613 Potassium bicarbonate.

(a) Potassium bicarbonate (KHCO_3 , CAS Reg. No. 298-14-6) is made by treating a solution of potassium carbonate with carbon dioxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23) of this chapter, and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food and infant formulas, in accordance with § 184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 3 percent in confections and frostings as defined in § 170.3(n)(9) of this chapter, and 0.02 percent in infant formulas.

§ 184.1619 Potassium carbonate.

(a) Potassium carbonate (K_2CO_3 , CAS Reg. No. 584-08-7) is produced by the electrolysis of potassium chloride followed by exposing the resultant potassium to carbon dioxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used in food as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23) of this chapter, and processing aid as

defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food, in accordance with § 184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.5 percent in baked goods as defined in § 170.3(n)(1) of this chapter, 0.01 percent in nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter, 3 percent in confections and frostings as defined in § 170.3(n)(9) of this chapter, 0.2 percent in dairy product analogs as defined in § 170.3(n)(10) of this chapter, and in soft candy as defined in § 170.3(n)(38) of this chapter, and 0.09 percent in sweet sauces as defined in § 170.3(n)(43) of this chapter.

§ 184.1736 Sodium bicarbonate.

(a) Sodium bicarbonate (NaHCO_3 , CAS Reg. No. 144-55-8) is prepared by dissolving sodium carbonate and treating the solution with carbon dioxide. As carbon dioxide is absorbed a suspension of sodium bicarbonate forms. The slurry is filtered, forming a cake which is washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used in food as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter, dough strengthener as defined in § 170.3(o)(6) of this chapter, flavor enhancer as defined in § 170.3(o)(11) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, propellant and aerating agent as defined in § 170.3(o)(25) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, surface-active agent as defined in § 170.3(o)(29) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food and infant food, in accordance with § 184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 6 percent in baked goods as defined in § 170.3(n)(1) of this chapter, 5.6 percent in nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter, 0.07 percent in dairy product analogs as defined in § 170.3(n)(10) of this chapter, 1.3 percent in grain products and pastas as defined in § 170.3(n)(23) of this chapter, 0.8 percent in hard candy and cough drops as defined in § 170.3(n)(25) of this chapter, 2.9 percent in processed fruit and fruit juices

¹ Copies may be obtained from: National Academy of Sciences, 2101 Constitution Avenue NW., Washington, D.C. 20037.

as defined in §170.3(n)(35) of this chapter, 1.8 percent in soft candy as defined in §170.3(n)(38) of this chapter, 0.8 percent in infant baked goods, 0.005 percent in infant formulas, and 0.6 percent or less in all other food categories.

§184.1742 Sodium carbonate.

(a) Sodium carbonate (Na_2CO_3 , CAS Reg. No. 487-19-8) is derived either from purified trona ore that has been calcined to soda ash or from trona ore calcined to impure soda ash and then purified. Sodium carbonate is also synthesized from limestone by the Solvay process.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used in food as an antioxidant as defined in §170.3(o)(3) of this chapter, curing and pickling agent as defined in §170.3(o)(5) of this chapter, flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter, pH control agent as defined in §170.3(o)(23) of this chapter, and processing aid as defined in §170.3(o)(24) of this chapter.

(d) The ingredient is used in food, in accordance with §184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.1 percent in baked goods as defined in §170.3(n)(1) of this chapter, 0.04 percent in nonalcoholic beverages as defined in §170.3(n)(3) of this chapter, 0.4 percent in confections and frostings as defined in §170.3(n)(9) of this chapter, 0.2 percent in gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter, 0.1 percent in processed vegetables and vegetable juices as defined in §170.3(n)(36) of this chapter, 0.3 percent in sweet sauces, toppings, and syrups as defined in §170.3(n)(43) of this chapter, and 0.05 percent or less in all other food categories.

§184.1792 Sodium sesquicarbonate.

(a) Sodium sesquicarbonate ($\text{Na}_2\text{CO}_3 \cdot \text{NaHCO}_3 \cdot 2\text{H}_2\text{O}$, CAS Reg. No. 533-96-0) is prepared by partial carbonation of soda ash solution followed by crystallization, centrifugation, and drying.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as a pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredient is used in cream, in accordance with §184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice utilizes a level of the ingredient sufficient to control lactic acid prior to pasteurization and churning of cream into butter.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

5. In Part 186 by adding new §§186.1736 and 186.1742 to read as follows:

§186.1736 Sodium bicarbonate.

(a) Sodium bicarbonate (NaHCO_3 , CAS Reg. No. 144-55-8) is prepared by dissolving sodium carbonate and treating the solution with carbon dioxide. As carbon dioxide is absorbed, a suspension of sodium bicarbonate forms. The slurry is filtered, forming a cake which is washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as a constituent of cotton and cotton fabrics used in dry food packaging materials.

(d) The ingredient is used at levels not to exceed good manufacturing practice.

§186.1742 Sodium carbonate.

(a) Sodium carbonate (Na_2CO_3 , CAS Reg. No. 487-19-8) is derived either from purified trona ore that has been calcined to soda ash or from trona ore calcined to impure soda ash and then purified. Sodium carbonate is also synthesized from limestone by the Solvay process.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as a constituent of food-packaging materials.

(d) The ingredient is used at levels not to exceed good manufacturing practice.

The Commissioner hereby gives notice that he is unaware of any prior sanction for the use of these ingredients in food under conditions different from those proposed herein or different from that in Part 181. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The regulation proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act (21 U.S.C. 342), and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on such sanction at any later time. This notice also constitutes a proposal to establish a regulation under Part 181, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to this proposal.

Interested persons may, on or before August 14, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Ad-

ministration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this proposal will not have a major economic impact as defined by Executive Order 11821 (amended by Executive Order 11949) and OMB Circular A-107.

Dated: May 17, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

NOTE.—Incorporation by reference was approved by the Director of the Office of the Federal Register on July 10, 1973, and is on file in the Federal Register Library.

[FR Doc. 16253 Filed 6-12-78; 8:45 am]

[4110-03]

[21 CFR Parts 314, 429 and 431]

[Docket No. 78N-0127]

DEFINITION OF "UNITED STATES"

Withdrawal of Proposal and Termination of
Rulemaking Proceeding

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposal.

SUMMARY: The Commissioner of Food and Drugs is withdrawing a proposal to define the term "United States" for establishing residency requirements or place of business requirements for authorized agents of foreign new drug applicants or manufacturers. Upon further consideration of the proposal, the Commissioner has concluded that rulemaking in this matter is not necessary.

EFFECTIVE DATE: June 13, 1978.

FOR FURTHER INFORMATION
CONTACT:

Phillip L. Paquin, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-7220.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 18, 1973 (38 FR 19130), the Commissioner issued a proposal to define the term "United States." The proposed rule would have amended §§310.3 and 429.40 (21 CFR 310.3 and 429.40) (formerly 21 CFR 130.1 and 164.2 respectively, both of which were recodified